DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431 and 457

[CMS–6026–F]

RIN 0938–AN77

Medicaid Program and State Children's Health Insurance Program (SCHIP); Payment Error Rate Measurement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule sets forth the State requirements to provide information to us for purposes of estimating improper payments in Medicaid and SCHIP. The Improper Payments Information Act of 2002 (IPIA) requires heads of Federal agencies to estimate and report to the Congress annually these estimates of improper payments for the programs they oversee, and submit a report on actions the agency is taking to reduce erroneous payments.

This final rule responds to the public comments on the August 28, 2006 interim final rule (71 FR 51050) and sets forth State requirements for submitting claims and policies to the CMS Federal contractors for purposes of conducting fee-for-service and managed care reviews. This final rule also sets forth the State requirements for conducting eligibility reviews and estimating case and payment error rates due to errors in eligibility determinations.

DATES: *Effective Date:* These regulations are effective on October 1, 2007.

FOR FURTHER INFORMATION CONTACT: Janet E. Reichert, (410) 786–4580.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Improper Payments Information Act of 2002

The Improper Payments Information Act of 2002 (IPIA), Pub. L. 107–300, enacted on November 26, 2002, requires the heads of Federal agencies annually to review programs they oversee that are susceptible to significant erroneous payments, to estimate the amount of improper payments, to report those estimates to the Congress, and to submit a report on actions the agency is taking to reduce erroneous expenditures. The IPIA directed the Office of Management and Budget (OMB) to provide guidance on implementation. OMB defines ''significant erroneous payments'' as annual erroneous payments in the program exceeding both 2.5 percent of program payments and $10 million (OMB M–03–13, May 21, 2003 and OMB M–06–23, August 10, 2006). For those programs with significant erroneous payments, Federal agencies must provide the estimated amount of improper payments and report on what actions the agency is taking to reduce them, including setting targets for future erroneous payment levels and a timeline by which the targets will be reached.

According to the OMB directive, Federal agencies must include in the report to the President and Congress: (1) The estimate of the annual amount of erroneous payments; (2) a discussion of the causes of the errors and actions taken to correct those problems, including plans to increase agency accountability; (3) a discussion of the amount of actual erroneous payments the agency expects to recover; (4) limitations that prevent the agency from reducing the erroneous payment levels, that is, resources or legal barriers; and (5) a target for the program's future payment rate, if applicable.

The Medicaid program and the State Children's Health Insurance Program (SCHIP) were identified by OMB as programs at risk for significant erroneous payments. OMB directed the Department of Health and Human Services (DHHS) to report the estimated error rates for the Medicaid and SCHIP programs each year for inclusion in the Performance and Accountability Report (PAR).

Through the Payment Accuracy Measurement (PAM) and Payment Error Rate Measurement (PERM) pilot projects that CMS operated in Fiscal Years (FYs) 2002 through 2005, we developed a claims-based review methodology designed to estimate State-specific payment error rates for all adjudicated claims within 3 percent of the true population error rate with 95 percent confidence. An ''adjudicated claim'' is a claim for which either money was obligated to pay the claim (paid claims) or for which a decision was made to deny the claim (denied claims).

B. CMS Rulemaking

Section 1102(a) of the Social Security Act (the Act) authorizes the Secretary to establish such rules and regulations as may be necessary for the efficient administration of the Medicaid and SCHIP programs. The Medicaid statute at section 1902(a)(6) of the Act and the SCHIP statute at section 2107(b)(1) of the Act require States to provide information that the Secretary finds necessary for the administration, evaluation, and verification of the States' program. Also, section 1902(a)(27) of the Act (and 42 CFR 457.950) requires providers to submit information regarding payments and claims as requested by the Secretary, State agency, or both.

Under the authority of these statutory provisions, we published a proposed rule on August 27, 2004 (69 FR 52620) to comply with the requirements of the IPIA and the OMB guidance. Based on the methodology developed in the pilot projects, the proposed rule set forth provisions for all States annually to estimate improper payments in their Medicaid and SCHIP programs and to report the State-specific error rates for purposes of our computing the national improper payment estimates for these programs. The intended effects of the proposed rule were to have States measure improper payments based on FFS, managed care, and eligibility reviews; to identify errors; to target corrective actions; to reduce the rate of improper payments; and to produce a corresponding increase in program savings at both the State and Federal levels.

After extensive analysis of the issues related to having States measure improper payments in Medicaid and SCHIP, including public comments on the provisions in the proposed rule, we revised our approach. Our revised approach adopted the recommendation to engage Federal contractors to review State Medicaid and SCHIP fee-for-service (FFS) and managed care claims (we define the term ''*claims*'' to include both managed care capitation payments and FFS line items) and to calculate the State-specific and national error rates for Medicaid and SCHIP. States will calculate the State-specific eligibility error rates. Based on these rates, the Federal contractor will calculate the national eligibility error rate for each program. We also adopted the recommendation to sample a subset of States each year rather than to measure every State every year. We adopted these recommendations primarily in response to commenters' concerns with the cost and burden to implement the regulatory provisions at the State level that the proposed rule would have imposed on States.

Since our revised approach departed significantly from the approach in the proposed rule, we published an interim final rule with comment period on October 5, 2005 (70 FR 58260). The October 5, 2005 interim final rule with comment period responded to the public comments on the proposed rule, and informed the public of our national contracting strategy and of our plan to measure improper payments in a subset

of States. Our State selection will ensure that a State will be measured once, and only once, every 3 years for each program. For each fiscal year, we stated that we expected to measure up to 18 States. We also stated that we would use a rotational approach to review the States' Medicaid programs. The rotation allows States to plan for the reviews because States know in advance in which year they will be measured. At the end of the first 3-year cycle, the rotation will repeat so that the FY 2006 States will be reviewed again in FY 2009; the FY 2007 States will be reviewed again in FY 2010; and the FY 2008 States will be reviewed again in FY 2011. The rotation will continue in this manner for future years.

In determining the Medicaid State selection, we grouped all States into three equal strata of small, medium, and large, based on the States' most recently available FFS annual expenditure data. We randomly selected up to six States from each stratum each year, until we selected all States for the first cycle of FY 2006 through FY 2008. We announced the Medicaid State selection rotation in the October 5, 2005 interim final rule and also through a State Health Official Letter released to all States on November 18, 2005.

In the October 5, 2005 interim final rule, we stated that it was still possible that States sampled for review would be required to conduct eligibility reviews as described in the proposed rule. We also announced our intentions to establish an eligibility workgroup to make recommendations on the best approach for reviewing Medicaid and SCHIP eligibility within the confines of current statute, with minimal impact on States and additional discretionary funding. We convened an eligibility workgroup comprised of DHHS (including CMS and, in an advisory capacity, the Office of the Inspector General (OIG)), OMB, and representatives from two States. We determined that States should conduct the eligibility measurement and developed an eligibility measurement methodology based on the workgroup's consideration of public comments, the examination of various approaches proposed in such comments, and the suggestions of the panel members.

The October 5, 2005 interim final rule also set forth the types of information that States would submit to the Federal contractors for the purpose of estimating Medicaid and SCHIP FFS improper payments and invited further comments on methods for estimating eligibility and managed care improper payments. We received very few comments regarding managed care and a number of comments regarding eligibility.

Based on the public comments and recommendations from the eligibility workgroup, we published a second interim final rule on August 28, 2006 (71 FR 51050), which set forth the methodology for measuring improper payments in Medicaid and SCHIP FFS, managed care, and eligibility in 17 States and invited further public comments on the eligibility measurement.

C. IPIA Compliance

We expect to be fully compliant with IPIA requirements by the year 2008. We measured Medicaid FFS improper payments in FY 2006 and plan to have all components (FFS, managed care, and eligibility) of Medicaid and SCHIP measured in FY 2007 for reporting in the FY 2008 Performance and Accountability Report (PAR).

These measurements in 17 States each year will produce State-specific component error rates as well as composite program error rates for the State's Medicaid and SCHIP programs. From the State-specific error rates, we will calculate national error rates for each of the components and for the Medicaid and SCHIP programs.

We expect State corrective actions to address the causes of error in each of the program components. As a result, we expect States will reduce their program error rates over the course of each measurement cycle which, in turn, should reduce the national error rates.

II. Provisions of the August 28, 2006 (Second) Interim Final Rule

We published a second interim final rule with comment period on August 28, 2006 that responded to comments on the October 5, 2005 initial interim final rule with comment period. In the August 28, 2006 interim final rule, we reiterated our national contracting strategy to estimate improper payments in both Medicaid and SCHIP fee-for-service and managed care claims and set forth the State requirements for estimating improper payments due to errors in Medicaid and SCHIP eligibility determinations. We also announced that a State's Medicaid and SCHIP programs would be reviewed in the same year.

A. Selecting SCHIP States for Review

After the October 2005 Medicaid State selection, we decided on the SCHIP State selection for the PERM measurement beginning with FY 2007. We determined that SCHIP could be measured in the same States selected for Medicaid review each fiscal year with a high probability that the SCHIP error rate would meet OMB requirements for confidence and precision levels.

We believe that paralleling the SCHIP and Medicaid measurements will minimize administrative complexities for both CMS and the States. Measuring both programs at the same time may further reduce the State cost and burden because States are able to plan activities for both measurements and may gain efficiencies by combining staff and resources for the reviews.

We announced in the August 28, 2006 interim final rule our decision to measure Medicaid and SCHIP in a State at the same time. We also sent a State Health Official Letter to all States regarding the SCHIP State selection on August 30, 2006. As with Medicaid, we stated that we expected to measure improper payments in all components of SCHIP in FY 2007 and beyond. The selection of States for the first PERM cycle of FY 2006 through FY 2008 is listed below. Note that, for States measured for Medicaid FFS in FY 2006, all three components of Medicaid and SCHIP will be measured in FY 2009.

MEDICAID AND SCHIP STATE SELECTION

FY 2006	Pennsylvania, Ohio, Illinois, Michigan, Missouri, Minnesota, Arkansas, Connecticut, New Mexico, Virginia, Wisconsin, Oklahoma, North Dakota, Wyoming, Kansas, Idaho, Delaware.
FY 2007	North Carolina, Georgia, California, Massachusetts, Tennessee, New Jersey, Kentucky, West Virginia, Maryland, Alabama, South Carolina, Colorado, Utah, Vermont, Nebraska, New Hampshire, Rhode Island.
FY 2008	New York, Florida, Texas, Louisiana, Indiana, Mississippi, Iowa, Maine, Oregon, Arizona, Washington, District of Columbia, Alaska, Hawaii, Montana, South Dakota, Nevada.

B. PERM Measurement Cycle

We stated in the August 28, 2006 interim final rule that the process for measuring improper payments, called the ''production cycle,'' under the national contracting strategy would take approximately 23 months per cycle. Using FY 2006 as an example, we provided the following table as an approximate overview of the PERM process. It is important to note that the process is fluid, so timeframes may fluctuate slightly depending on such factors as the complexities of the reviews.

EXAMPLE OF THE PERM PRODUCTION CYCLE: FY 2006

[Note: only illustrates Medicaid FFS]

Timeframe	Event
December 1, 2005	• States submit medical policies in effect for the review period to the DDC.
January 15, 2006	• States submit 1st quarter FY 2006 (October–December 2005) adjudicated claims to the SC.
February 1, 2006	• State submits 1st quarter FFS policy updates to the DDC.
April 15, 2006	• States submit 2nd quarter FY 2006 (January–March 2006) adjudicated claims to the SC.
May 1, 2006	• States submit 2nd quarter policy updates to the DDC.
July 15, 2006	• States submit 3rd quarter FY 2006 (April–June 2006) adjudicated claims to the SC.
August 1, 2006	• States submit 3rd quarter policy updates to the DDC.
October 15, 2006	• States submit 4th quarter FY 2006 (July–September 2006) adjudicated claims to the SC.
November 1, 2006	• States submit 4th quarter policy updates to the DDC.
Throughout PERM process	• States identify and resolve differences in review findings with the RC.

C. Use of Federal Contractors to Review FFS and Managed Care Claims

In the August 28, 2006 interim final rule, we reiterated that, under the national contracting strategy, we would use Federal contractors to measure Medicaid and SCHIP FFS and managed care improper payments. We believe the use of more than one CMS Federal contractor allows for the award of contracts in areas of specialization and expertise, minimizes potential problems with the error rate measurement process if one contractor experiences operational difficulties, and provides us with optimum oversight. However, we may revise our use of multiple contractors in the future if warranted by our experience as the program matures, for example, if we can gain efficiencies. For FYs 2006 and 2007, we awarded three contracts: (1) A statistical analysis contract; (2) a documentation/database contract; and (3) a review contract.

The statistical contractor (SC) collects adjudicated claims data, determines the sample size, draws the sample, and calculates the State and national error rates. The documentation/database contractor (DDC) standardizes State data, collects and stores State medical and other related policies, and requests the medical records from providers for the FFS medical reviews. The review contractor (RC) conducts the medical and data processing reviews on the States' FFS and managed care claims.

In the August 28, 2006 interim final rule, we indicated that the States' responsibilities to support the improper payments measurement for both Medicaid and SCHIP would include submission of information on managed care. We stated that the States selected for review would submit to the SC the following information for Medicaid and SCHIP:

• All adjudicated FFS and managed care claims information from the review year on a quarterly basis, with FFS claims stratified into seven strata by service type and one additional stratum for denied claims;

• Information on claims that were selected as part of the sample, but which changed in substance after selection (for example, successful provider appeals); and

• Adjustments made within 60 days after the adjudication dates for the original claims or line items, with sufficient information to indicate the nature of the adjustments and to match the adjustments to the original claims or line items.

We required States to provide stratified FFS claims data because we believed that stratifying the claims by service type would improve the efficiency of the sampling methodology by distributing the claims in the sample in proportion to the dollar share in the universe. Stratification allows services with a larger dollar share to compose a larger share of the sample and reduces the variance in the sample. Stratifying the claims also allows for smaller sample sizes and for the identification of errors in specific service types so that States would have information that could be helpful to target causes of errors.

Based on the annual expenditure data, the SC would determine the State's sample size and, for FFS claims, the sample size for each of the eight total strata. These strata were established during the pilot projects based on the total share of dollars. States had already grouped their claims similarly in their Medicaid Management Information System (MMIS); therefore, we believed that the stratification of claims for submission would not be burdensome to States.

We established the following strata: (1) Hospital services; (2) long term care services; (3) other independent practitioners and clinics; (4) prescription drugs; (5) home and community based services; (6) other services and supplies (for example, durable medical equipment, clinical lab tests, and x-rays); (7) primary care case management; and (8) denied claims.

From the State's quarterly adjudicated claims data, the SC would randomly select a sample of FFS and managed care claims each quarter. Each selected FFS claim would be subjected to a medical and data processing review. Managed care claims would not be stratified or subjected to medical reviews because the payments made to a managed care plan are based on a set fee from a predetermined capitation agreement, rather than for the specific service(s) provided. We expected that the sample size would be 1,000 FFS claims and 500 managed care claims per State per program in order to achieve a 3 percent precision level at the 95 percent confidence level (based on a range estimated during the PAM/PERM pilots).

For review of the sampled claims, States would provide the DDC the following information for Medicaid and SCHIP:

• All medical and other related policies in effect for the review year and any quarterly policy updates;

• Current managed care contracts, rate information, and any quarterly updates to contracts and rates for the review year for SCHIP and, as requested, for Medicaid; and

• Upon request from the contractor, provider contact information that has been verified by the State as current.

States selected for review also would provide the RC the following information for Medicaid and SCHIP:

• Systems manuals for data processing reviews. (If a State's medical and data processing policies are intertwined, the State may send the policies to the DDC. The DDC would then identify the data processing policies so the RC could access them through the DDC.)

• Repricing information, as requested by the RC, for claims that the RC determined to be improperly paid. The RC would request that States submit the price that should have been paid so that, for claims that were found to be in error, the RC would be able to determine the amount of the improper payment.

The August 28, 2006 interim final rule also set forth a difference resolution process whereby States would be provided disposition reports listing the contractor's review finding on each claim. Based on these reports, States would be able to dispute error findings.

When the reviews were completed, the SC would estimate the State-specific error rates for the FFS and managed care components of the Medicaid and SCHIP programs. States (using the eligibility methodology set forth in the August 28, 2006 interim final rule to conduct eligibility reviews beginning in FY 2007) would calculate and report the State-specific eligibility error rates to us. These measurements also will produce component error rates for the State's Medicaid and SCHIP programs. From the State-specific error rates, we will calculate national error rates for each of the components and for the Medicaid and SCHIP programs.

Once the State-specific and national error rates were estimated, the States would develop and send to us corrective action reports describing corrective actions that the States would implement to address the major causes of improper payments. The States would review their error rates, determine root causes of error-prone areas, and develop corrective actions to address the major error causes for purposes of reducing the payment error rates. States selected for review would provide us with the following information for Medicaid and SCHIP:

• A corrective action report for purposes of reducing the State's payment error rates in the FFS, managed care, and eligibility components of the program; and

• Other information that the Secretary determined necessary for, among other purposes, estimating improper payments and determining error rates in Medicaid and SCHIP.

We stated that we would request information we found during the course of measuring each program that would improve the process, produce more accurate error rates, or reduce the cost and burden on either or both the State and Federal governments. Similarly, we stated that, if we determined that we were collecting specific information that did not add value to the error rate measurement or was not productive to collect, we would discontinue that collection.

D. Eligibility Measurement

In the August 28, 2006 interim final rule, we set forth the eligibility measurement methodology developed through the eligibility workgroup and through our consideration of public comments submitted in response to the October 5, 2005 initial interim final rule. The eligibility measurement methodology is summarized below:

• A State would review program eligibility in the year it was scheduled for review for FFS and managed care improper payments. The eligibility reviews would be conducted by a State agency that was functionally and physically independent of the State agency making the program policy and eligibility determinations.

• The Medicaid and SCHIP eligibility sample universes would consist of both active cases (individuals enrolled in the program) and negative cases (individuals denied or terminated from the program).

• Medicaid and SCHIP cases in the active universe would be stratified into three strata: (1) Applications, (2) redeterminations, and (3) all other cases. Negative case action samples would not be stratified in either program.

• A State would calculate its eligibility error rates for active cases (including undetermined cases) and negative cases.

• States would submit the following to CMS:

—A sampling plan for approval (which would be submitted 60 days before the beginning of the fiscal year selected for review);

—A monthly sample selection list that identified the cases selected for review (to be submitted each month and before commencing the reviews);

—Detailed findings on the cases reviewed;

—Summary findings on the cases reviewed; and

—State-specific case and payment error rates for active cases, case error rates for negative cases, the number and amount of undetermined cases, and the total amount of payment from all undetermined cases in the active case sample, to be submitted by July 1 after the end of the fiscal year under review.

We invited further comment on this methodology for measuring improper payments due to errors in eligibility determinations.

III. Analysis of and Responses to the Public Comments on the August 28, 2006 Interim Final Rule

We received a total of 33 comments: 28 from State agencies, 3 from consumer advocacy and other groups and 2 from individuals. These commenters reiterated some of the comments from the proposed rule to which we responded in the October 5, 2005 and August 28, 2006 interim final rules. Although we are not required to respond to these comments again, we are summarizing the comments in this final rule and providing our responses for the convenience of the reader. Below are the comments on the August 28, 2006 interim final rule and our responses.

Most comments responded to our invitation for further comment on the PERM eligibility measurement process. Commenters also indicated that, although the August 28, 2006 interim final rule significantly reduced the burden on the States by using a Federal contracting strategy and limiting State selection to once every 3 years, they believed that the August 28, 2006 interim final rule still placed an undue technical and financial burden on the States to assist the Federal contractors.

A. Purpose, Basis, and Scope

1. Payment Error Rates

Comment: Several commenters asserted that a State error rate is not required by IPIA and funds are wasted in establishing a payment error rate. The commenters also maintained that State audits could identify improper payments. The commenters stated that a national sampling framework should be used to measure a national error rate, and that CMS should abandon the proposed State-level error rate in favor of a national error rate and sampling plan.

Response: As we observed in the October 5, 2005 and August 28, 2006 interim final rules, the IPIA requires the Secretary to estimate the amount of improper payments in programs and activities that are susceptible to significant improper payments and report those estimates to the Congress. OMB has identified Medicaid and SCHIP as programs at risk for significant

improper payments. Because States administer these programs and because there is wide variation in States' coverage, eligibility, benefit, and reimbursement policies for these programs, we must rely on State-specific information to develop State-level estimates as the basis for a national program error rate.

In addition, even though State audits may identify improper payments, we could not be confident that States' audit procedures would be similar and would be consistently applied nationwide or would produce statistically reliable information on which a national rate could be based. Finally, we have stated that the PERM program is intended to fulfill the requirements of the IPIA; it is not intended to supplant, enhance, or change other program integrity activities in which the States are currently engaged.

Comment: One commenter suggested that the national error rate be computed using State error rates that are weighted against dollar volume in other States to ensure that each State's contribution to the error rate is clear, balanced, and consistently calculated at all levels of data analysis.

Response: The national error rate is calculated as the outcome of a two-stage sampling process. States were placed into one of three strata. These strata consist of the large, medium, and small States as measured by Medicaid expenditures. For each of the three rotations, 17 States were randomly selected from three strata. Beginning in FY 2007, for the States sampled in each year, claims and payments are sampled for Medicaid and SCHIP fee-for-service and managed care. Sufficient numbers of claims and payments are sampled to estimate an error rate for the State at a precision level of plus or minus 3 percentage points with 95 percent confidence. Then, within each of the three strata, an error rate is calculated to represent the error rate of that stratum. Finally, a national error rate is calculated by computing the error rates across the three strata, where each stratum's rate is weighted by the share of expenditures for that program represented by its strata. The variance in this estimate is calculated by taking into account: (1) The variance of the error rate of the individual States in the sample, and (2) the variance in the original sample of States from the three strata. The error rate is based on the total error, not the State or Federal share.

Comment: One commenter suggested that States should be allowed to calculate error rates based on either the difference method or ratio method.

Response: Our statistical contractor will calculate the State-specific error rates for FFS and managed care. In general, the ratio method of estimating the error rate is formed using data from the sample. From the sample, the dollar value of claims or payments in error enters the numerator, while the dollar value of payments (both those made in error and those that are valid) enters into the denominator. This ratio is the error rate.

In general, the ''difference'' estimator is calculated as follows. The dollar value of each error (the difference between what should have been paid and what was paid) in the sample is added, with weights equal to the inverse of the sampling frequency for the respective claim or line item. This provides an estimate of the total dollars in error for the universe or population for which the inference is made. This becomes the numerator of the error rate. The denominator of the error rate is actual payments made for the universe or population. The denominator is non-stochastic, that is, non-random. This ratio, then, provides an estimate of the error rate.

Because the actual payments made by the State for the universe or population may not be available when we calculate the error rate, we plan to use the ratio estimator.

Comment: A commenter observed that, in the August 28, 2006 interim final rule, we responded to a comment regarding the likelihood of achieving a national error rate by aggregating error rates from all the States' programs with their inherent variations. We stated that, ''(b)y drawing a stratified random sample of States and then reviewing a random sample of claims within each of those States (using each State's program policies), we are able to obtain an estimate of the national error rate without having to conduct reviews on all claims. This methodology will produce the estimate and the precision level of the estimated national error rate, within the parameters set by OMB.'' The commenter asserted this logic is circular and stated that more information is needed to explain how this process would work.

Response: The process is based on sampling. By sampling, one can obtain an estimate of a population parameter, such as the mean dollar value of a Medicaid claim for a State, without having to examine every claim in that State's universe. The larger the sample size, the more precise the estimate of the mean value will be. For most populations, one can typically obtain a very precise estimate of the population parameters, such as the mean, by sampling far fewer than the entire population or universe. Based on the outcome of the sample, one can make an inference regarding the values of the true population mean, for example, and a statement of the probability or likelihood that a small range around the sample estimate captures the population's true mean.

The national error rate is calculated as the outcome of a two-stage sampling process. First, States are sampled. Then, claims are sampled within the State.

States were placed into one of three strata. These strata consist of the large, medium, and small States as measured by Medicaid expenditures. For each year, a total of 17 States were randomly selected from the three strata. For States sampled in each strata, claims and payments are sampled for Medicaid and SCHIP fee-for-service and managed care. A sufficient number of claims and payments are sampled to estimate an error rate at a precision level of plus or minus 3 percentage points with 95 percent confidence for that State. Then, within each of the three strata, an error rate is calculated based on the States sampled in that stratum. Finally, a national error rate is calculated by estimating the error rate for the population of all States as a weighted average of the error rates within each stratum. The variance in this estimate is calculated by taking into account the variance of the error rate of the individual States in the sample and the variance in the original sample of States from the three strata.

Comment: A commenter would like to know the operational benefit of a national error rate to the States if they will be measured against their individual rates rather than a national average.

Response: The Improper Payments Information Act of 2002 (IPIA) requires CMS to estimate and report to the Congress annual estimates of improper payments. The national error rate for SCHIP and Medicaid will be reported to the Congress as required by law. States will use their State-specific error rates to implement corrective action plans. We believe that these plans will ultimately reduce the national error rate.

Comment: A commenter asked what assurance States would have that comparisons among States would not be made when the error rates were reported. Because of the wide variation in States' Medicaid and SCHIP programs, this assurance is needed in order to reassure States that unwarranted comparisons are not being made.

Response: We agree that care should be taken in comparing the State error rates due to variation in State programs.

Comment: A commenter requested that CMS develop methods to communicate with States regarding their responsibilities, timelines, and completion expectations.

Response: We have communicated with States through kick-off calls and one-on-one calls with each State involved in each year's measurement. In addition, we post all instructions, letters and questions and answers on our CMS PERM Web site at *http://www.cms.hhs.gov/PERM* for all States to review.

Comment: A commenter stated that, since PERM is measured in a 3-year cycle, the ''national average'' error rate cannot be compared year-to-year.

Response: We believe there are several approaches to assess the improvement in the reduction of improper payments year-to-year and over the years.

Comment: Two commenters believed that State program integrity efforts are in jeopardy because claims from providers under active fraud investigation are included in the universe. The commenters believed that (1) The error rate will be inflated because fraudulent and abusive providers are not likely to respond to requests for medical records; (2) providers can create, alter, or destroy documentation and evidence when they are alerted that their claims are investigated; and (3) false, fraudulent, and abusive claims can only be identified by interviewing recipients and reviewing medical records.

Response: We do not intend to jeopardize States' provider fraud investigations based on our review of FFS and managed care claims. Therefore, if a FFS or managed care claim sampled under PERM is part of a fraud investigation and the State notifies the statistical contractor of this fact, the claim will not be subject to review under PERM. However, we will cite the claim as an error. We believe the State, in this instance, also believes the claim is in error since the State is investigating the provider for fraud. For purposes of the eligibility review, which is conducted on individual beneficiary cases rather than claims, cases under beneficiary fraud investigation are excluded from review.

Comment: A commenter asked for clarification on whether the IPIA is intended to root out provider fraud or challenge program enrollment decisions. The commenter stated that those functions are under the purview of other Federal and State initiatives.

Response: We agree that the IPIA is not intended to root out these problems. The IPIA is intended to identify improper payments, and provider fraud may be discovered during the course of the measurement. In addition, erroneous Medicaid and SCHIP program enrollment decisions may be discovered during the eligibility reviews. The discovery of these problems would be addressed by the State through corrective actions.

Comment: A commenter indicated that the rule does not explain if extrapolations will be conducted and if error rates will be reported based on claims, dollar amount, or both.

Response: The method for estimating error rates is based on sampling from the population or universe. From the sample, inferences (or extrapolations) are drawn regarding specific population or universe values, such as the error rate for the population. The active case eligibility error rates will be dollar-weighted error rates. The dollars assigned to the case will be those associated with the claims that are collected for the recipient. The sample sizes for the active cases were constructed to achieve an estimate of the State's dollar-weighted error at a precision level of plus or minus 3 percentage points with 95 percent confidence. The State level active case eligibility error rates will be a component of a national active case eligibility error rate. A simple binomial error rate (valid/invalid) will be calculated for the active case error rate, and a binomial (valid/invalid) error rate will be calculated for negative cases.

The Medicaid and SCHIP error rates for both fee-for-service and managed care will be calculated and reported based on the dollar value of the line items or payments sampled. The sample sizes were constructed to achieve a precision level for each of the programs (Medicaid and SCHIP fee-for-service and managed care) of plus or minus 3 percentage points with 95 percent confidence. The State level error rates will also be used to estimate national error rates for these programs, which are expected to achieve a precision level of plus or minus 2.5 percentage points with 90 percent confidence.

To summarize, the methodology is to sample from the population or universe, and then use the sample results to infer or extrapolate the error rate for the population.

2. State Selection

Comment: A commenter stated that States were led to believe that each program would be measured on an alternating or rotational basis. By measuring Medicaid and SCHIP in the same year, the commenter believes that CMS has unilaterally increased the State's cost and burden by 100 percent. According to the commenter, this decision is contrary to the supporting statement issued with the initial request to gain OMB approval (71 FR 30409) published May 26, 2006.

Response: We believe that State cost and burden could actually be reduced by measuring both programs in the same year. States would have to measure errors in both programs at some point. By evaluating them simultaneously, we believe efficiencies will be gained that may lower costs and burden. We stated in both published interim final rules that we would rotate the States, not the programs. We reiterate, in this final rule, that each State will be measured on a rotational basis.

Comment: A commenter stated that the proposed random selection of States to be reviewed under the PERM program makes it difficult to predict the resources needed for PERM-related activities. If not forthcoming, States could be held responsible for time delays in the program.

Response: In the August 28, 2006 interim final rule, we stated that we will use a rotational approach to review the States in Medicaid and SCHIP. We released instructions explaining the selection of the States to be reviewed under the PERM program through an October 10, 2006 State Health Official letter. This information was also posted on the CMS PERM Web site at *http://www.cms.hhs.gov/PERM*. Further, we stated that we believe that the rotation will allow States to plan for the reviews because States will know in advance in which year they will be measured.

3. Use of National Contractor

Comment: A commenter stated that Generally Accepted Government Auditing Standards (GAGAS) require States to review and comment on contractor-generated PERM working papers and findings for quality control purposes. The commenter asserted that the contractor's findings should not be deemed final or actionable until this review is complete. In addition, the commenter stated that the cost of this review must be included in the rules, which, according to the commenter, does not appear to be the case.

Response: The PERM program does not require States to use GAGAS. GAGAS is issued by the Comptroller of the United States as auditing standards for governmental audits. The PERM program is not an audit and as such, GAGAS would not be applicable. However, under PERM, States have the

opportunity through the difference resolution process to review error findings. States also have the opportunity to further dispute error findings by appealing to CMS.

Comment: A commenter applauded the use of national contractors but did not believe the contractors have the required knowledge to complete the reviews under CMS' current schedule. The commenter believed additional time is needed for the transfer of knowledge from State to contractor.

Response: The contractors will work closely with the States during the measurement process to ensure that program knowledge is transferred. We believe this will help mitigate delays in the process that might be encountered otherwise.

Comment: A commenter asked how many days after the quarter ends would State information have to be submitted to the statistical contractor. The commenter stated that no details were provided on page 51053 of the **Federal Register** publication of the August 28, 2006 interim final rule.

Response: Our statistical contractor's instructions request that State information be submitted to the statistical contractor no later than 15 days after the quarter ends.

Comment: A commenter asked CMS to further clarify the format in which States will be required to submit data for PERM compliance purposes and whether the data would need to be coded.

Response: The operational details are contained in the instructions that the statistical contractor sends to the States being measured at the beginning of each quarter.

Comment: A commenter stated that the delay in collecting provider documentation does not allow enough time for a State to respond to any findings or perceived errors. The commenter does not believe that hiring three contractors is effective in measuring error rates.

Response: We believe that having three contractors is effective because the program is not jeopardized or substantially delayed if one contractor experiences problems; the other contractors could continue their respective aspects of the measurement. We agree that the 90-day timeframe to collect medical records from providers may not allow States adequate time to resolve errors with the RC through the difference resolution process. In order to expedite the difference resolution process within the overall timeframe for calculating annual error rates under PERM, and provide States with adequate time to respond to our contractor's proposed findings, we will issue guidance instructing our national contractors to request that providers, in compliance with our regulations at 42 CFR 431.107(b)(2), 431.970, and 457.720, submit medical records no later than 60 days after issuance of the contractor's letter requesting such records. This will provide additional time for the State and contractor to analyze and resolve discrepancies.

4. State Input into the Program

Comment: One commenter disagreed with CMS' statement that States have been active participants in the PERM regulatory process. The commenter stated that CMS has not provided an acceptable forum for State participation in the development of PERM regulation, and that only two States were involved in meetings with CMS during the development of the regulation. In addition, the commenter indicated that CMS has not been present on three all-State calls regarding PERM regulation, and that when CMS is present on calls, CMS does not provide substantive responses to questions and points of clarification from the States. The commenter concluded that States cannot make reasonable comments and suggestions when CMS does not provide States with sufficient information.

Response: The two States participated in the eligibility workgroup; they did not participate in developing the entire PERM regulation. Consistent with the rulemaking process, we have provided a vehicle by which we review all timely public comments submitted to us. Through this process, we have received valuable assistance in developing an error rate measurement procedure that we believe is both sensitive to the burdens that States must bear in meeting their responsibilities, as well as one that allows us to uphold the duties that we must carry out to be in compliance with the IPIA.

B. Methodology

Comment: Commenters stated that CMS should provide a detailed timeline for the PERM sampling year for claim and eligibility reviews, so that States would understand the schedule and deadlines. They indicated that this timeline should identify all three contractor activities and expected State responsibilities (for example, claim delivery and sampling schedule dates and required State documentation due dates needed by contractors to comply with CMS contract deadlines). In addition, the commenters noted that States have suggested that, for each PERM State being reviewed, the contractors should prepare monthly project planning documents to CMS and the States that would explain delays, barriers, or other issues that have arisen and the contractor's plans to resolve any problem areas.

Response: We provided an overall timeline of the measurement process in the August 28, 2006 interim final rule (using the FY 2006 Medicaid FFS measurement as an example) to identify when States should submit needed information. We have included the timeline again in this final rule (see ''Example of the PERM Production Cycle: FY 2006'' illustration) for the reader's convenience. In addition, we have held kick-off calls, State-specific calls, component review calls, and provided instructions to States selected for the FY 2006 and FY 2007 measurements, so States would understand the schedule and deadlines for the FFS and managed care claims data submission. We intend to provide the same guidance to States selected for the FY 2008 and FY 2009 measurements. The timeline for the eligibility measurement is attached to the eligibility instructions, which can be found along with the claims submission instructions, on the CMS PERM Web site at *http://www.cms.hhs.gov/PERM*.

Sampling

1. Exclusions From the Claims Universe

Denied Claims

Comment: Two commenters suggested that CMS remove denied claims as a review stratum. The commenters stated that there is an increased burden on States to produce a list of adjudicated denied claims and track re-billings of denied claims. The commenters also noted that there is difficulty in determining the sample size based on dollar value when the value of the denied claim is zero. The commenters recommended convening a workgroup to determine a methodology to measure errors in denied claims.

Response: Denied claims could be underpayments, and IPIA requires the inclusion of underpayments in our measurement. We believe it is as important to know when claims and eligibility have been wrongfully denied as when they have been wrongfully paid and approved. Furthermore, the sample size is determined by our statistical contractor, not the States. Finally, the methodology to measure errors in denied claims was developed by CMS and States during PAM/PERM pilots. Therefore, we are not adopting the suggestion to convene a workgroup to revisit this matter.

2. Sampling Issues

Comment: A commenter noted that the PERM stratification requirements are complex and would likely pose a challenge for its systems.

Response: We agree that stratifying Medicaid FFS claims has posed challenges for States. Many States measured in FY 2006 had difficulties stratifying the claims. Therefore, we are revising the requirement at § 431.970(a)(1) to remove the stratification of Medicaid and SCHIP FFS claims by service requirement. This approach will further reduce State burden since States would need only to submit the universe data. We believe we can achieve greater sampling efficiency by stratifying the FFS claims by dollar value rather than by service. The Federal contractor will stratify the claims by dollar value.

Comment: A commenter stated that CMS did not provide a rationale for the following statement in the August 28, 2006 interim final rule: ''We did not adopt the recommendation to select a nationwide sample because we believed that it was not the best overall method to meet the requirements of the IPIA and OMB guidance. There is no national sampling framework for SCHIP claims * * *'' The commenter maintained that the absence of a national sample framework for SCHIP does not mean that one could not or should not exist.

Response: We do not believe a national sample is the best method to achieve IPIA compliance. The Medicaid and SCHIP programs are State-administered, and as such, we think it is necessary for States to participate in part of the measurement process. We considered the suggestions made by commenters on the past interim final rules and determined that we would not adopt this recommendation.

Comment: A commenter asked whether the universe of claims includes pharmacy, mental health, and substance abuse claims.

Response: Yes, pharmacy, mental health, and substance abuse claims are included in the universe of claims.

Comment: Since the annual sample size is 1,000 FFS claims per State per program, a commenter stated that the State's SCHIP program will likely be disproportionately oversampled, since its State represents only approximately 10 percent of the total United States population.

Response: From a sampling perspective, there is generally no difference between a small and large population. Specifically, a property of sampling is that, once the population size exceeds about 10,000, the population can be treated as if it were an infinite population. In other words, statistically speaking, beyond a universe of about 10,000, population differences do not have a significant effect on sample size.

Comment: A commenter asked CMS to clarify each sample size and methodology for each area of the PERM project. The commenter stated that in all correspondence released by CMS to the States, the sample sizes and methodologies have varied, which has made it difficult for States to determine what is expected from them.

Response: PERM measures three components in Medicaid and three components in SCHIP: FFS, managed care, and eligibility. For FY 2006, the FFS sample size is 1,000 claims annually per program. These claims are subject to data processing and medical reviews by our contractor. For FY 2006, the managed care sample is 500 claims annually per program. These claims are subject to data processing review only by our contractor. For FY 2006, the eligibility sample size is 504 active cases and 204 negative cases (not claims). Reviews to verify eligibility are done by the States. Future sample sizes are subject to change as necessary depending on such factors as lessons learned or other situations impacting the timely and accurate error rate measurement.

Comment: Commenters asked when FY 2007 States could expect to receive additional information regarding the data elements that would be required for data submission.

Response: The statistical contractor sends instructions out to each State 45 days before the beginning of each fiscal year.

3. Medical Records Collection

Comment: A commenter asked if it was the State's responsibility to pursue information identifying which providers have not submitted requested medical records and whether the documentation/database contractor would provide this information to the State.

Response: The documentation/database contractor will request the medical records directly from providers for the FFS medical reviews. The contractor will follow-up with providers who have not submitted medical records. The contractor will notify the State of providers who have not submitted medical records. The State can opt to follow-up with these providers.

Comment: A commenter stated that, when the documentation/database contractor receives the medical records from the provider, it is imperative that the contractor immediately review the records for completeness and appropriateness of documentation. The commenter stated that the review should not be delayed until the medical review occurs because such delay increases the likelihood of a claim found in error.

Response: The DDC is responsible only for the collection of medical records and does not have the clinical expertise to determine the completeness of these records. However, the review contractor (who conducts the medical reviews) will notify the DDC if additional information is needed during the medical review, and the DDC will follow-up with the provider to obtain the specific information needed. Insufficient documentation errors are cited when the provider does not respond to the request for additional information or does not provide the additional information within 14 days of the request.

Comment: A commenter stated that our assurances related to the receipt of documentation before considering an error for lack of documentation were insufficient. According to the commenter, it is unreasonable to suggest that providers will respond timely to three written and oral requests during a 90-day time period. The commenter believed the documentation/database contractor should be required to obtain documentation throughout the entire review year.

Response: Our experience has shown that our provider response rate to requests for medical records is excellent, and that most providers submit records within 30 days of the original request. Therefore, we do not believe that the timeframe should be extended to include the entire review year and are not adopting this recommendation. In fact, given that the provider response rate is good and considering States' concerns with the 90-day timeframe impeding on the difference resolution process, we are considering reducing the timeframe, for example, to no later than 60 days from the date of the letter sent by the contractor requesting the medical records. If we decide this is worthwhile, we will issue a policy instruction to that effect.

Comment: A commenter stated that, since the documentation/database contractor will request medical records for the PERM program from a provider, CMS should consider methods to minimize the duplication of efforts since the State will have already received documentation from the provider.

Response: We agree that duplication of effort should be minimized wherever possible as long as the documentation is complete, comprehensive, and timely.

4. Adjustments to Claims

Comment: A commenter requested clarification regarding whether the 60-day adjustment timeframe pertains to managed care claims or whether it only applies to FFS claims.

Response: The 60-day adjustment timeframe pertains to both FFS and managed care claims. Adjustments made within 60 days of the original paid date will be included in the review process, which will consider the net amount paid (original paid amount with additions and subtractions due to adjustments that occurred within 60 days) in calculating the error rate.

States will submit adjustments for managed care payments selected in the random sample each quarter. These may include retroactive rate changes, rate cell assignment corrections, and takebacks for beneficiaries who lost eligibility.

Note that, while States may have policies that allow adjustments to be made more than 60 days after the original paid date, only the adjustments made within 60 days are considered for PERM purposes.

Comment: Several commenters expressed concern that § 431.970(a)(8) requires States to make adjustments to managed care capitation claims within 60 days of the adjudication date. The commenters maintained that States needed a longer timeframe to reconcile and adjust payments before the payments were classified as errors. One commenter observed that its SCHIP program has a reconciliation process in place that makes positive and negative adjustments to capitation payments to health plans on a retroactive basis; this process takes longer than 60 days. Some other commenters asserted that adopting a 60-day window for adjustments is contrary to the time periods now allowed in many States. One of the commenters recommended that CMS extend the adjustment timeframe to a minimum of 4 months.

Response: We responded to this comment in the August 28, 2006 interim final rule (70 FR 58260). We understand the commenter's concern; however, States have varying timeframes in which claims are adjusted, and we cannot extend the timeframe in a manner that would accommodate all States' practices. We noted in the August 28, 2006 interim final rule that the 60-day timeframe was agreed upon by States and CMS during the development of the review methodology under the PAM pilot projects as a reasonable timeframe. The 60-day timeframe allows for claims adjustments while maintaining a timeline that also allows for completing the reviews and computing and reporting the error rates in time for inclusion in the PAR.

If we extend the timeframe to a point beyond 60 days, we cannot be assured that the error rate measurement process will be completed in time to report the error rate. Accordingly, we are not adopting this recommendation.

Comment: A commenter stated that a bottom-line error rate must net overpayments and underpayments as already required by the HHS Office of Inspector General Corporate Integrity Agreements (*http://oig.hhs.gov/fraud/cia/docs/ciafaq1.html*).

Response: OMB guidance M–06–23, published on August 10, 2006, states that ''incorrect amounts are overpayments and underpayments (including inappropriate denials or payment of services).'' OMB guidance further directs that the estimate of improper payments is a gross total of both over and under payments. The OIG guidance that the commenter refers to is for a different purpose and does not apply to PERM.

Comment: If a claim is sampled that is a reversal of a prior claim, a commenter asked whether States would need to provide the original claim, which may have been outside the timeframe.

Response: The State will sample original claims only because no stand alone adjustments to claims are included in the universe. In other words, the State will sample original claims only and make any necessary adjustments within 60 days of the paid date for the claims after the sample is selected. These consolidated and adjusted claims would then be reviewed to determine if they were correctly paid.

Comment: A commenter asked whether adjustments to claims made within 60 days from the adjudication dates for the original claims or line items should be provided for the universe, or just for the selected sample.

Response: Adjustments should be provided for the selected sample only.

5. Medical and Data Processing Reviews

a. Methodology

Comment: A commenter recommended separating out claims for residential care services within the overall estimate of the State payment error rate, and suggested that CMS perform a quantitative and qualitative analysis to determine the underlying reasons for the payment errors in this category through surveys. CMS could then utilize the data to correct the errors by giving States and providers additional training where needed.

Response: Although we appreciate the commenter's recommendation, we are not adopting it. States are responsible for performing error rate analyses and for taking appropriate corrective action(s). The requirements for the PERM program do not preclude a State from independently evaluating any area within its Medicaid or SCHIP program that may trigger a concern or may be vulnerable to payment errors. In addition, it does not prevent a State from taking appropriate corrective action.

b. Medical Reviews

Comment: A commenter suggested that CMS should allow findings of ''undetermined'' for the medical claims reviews as is permitted for the eligibility reviews. The commenter believed that failure to recognize an ''undetermined'' result due to missing or insufficient documentation to support the medical reviews of FFS claims could produce artificially inflated payment error rates.

Response: Requirements to document eligibility can vary by State. However, all medical records should contain documentation to support services rendered. We believe that claims should not be considered correctly paid when documentation is missing to support the payment or does not justify the payment. Therefore, we are not adopting this recommendation.

Even though the total payment error rate will include documentation errors, as we stated in the August 28, 2006 interim final rule, the findings by our Federal contractors will distinguish errors due to missing documentation and insufficient documentation from other types of errors. As a result, States will be able to target corrective actions appropriately.

Comment: A commenter asked why claims will be counted in error if medical records cannot be provided.

Response: The FFS claims subject to medical review and lacking documentation to support the payments are considered errors because there is no evidence available to determine the appropriateness and medical necessity of the payments.

Comment: The August 28, 2006 interim final rule stated that ''[e]ach selected FFS claim will be subjected to a medical and data processing review.'' According to a commenter, this statement contradicts previous **Federal Register** information and PAM/PERM guidance on medical review of cross-

over claims. The commenter asks CMS to clarify the reported contradiction.

Response: The statement in the August 28, 2006 interim final rule was intended to provide a broad description of the PERM measurement process. In response to this comment, we are clarifying that cross-over claims (claims that are paid by both Medicare and Medicaid for services provided to Medicaid beneficiaries) are not subject to medical review.

c. Data Processing Reviews

Comment: A commenter asked how data processing reviews would be conducted if a SCHIP program did not process its own claims but instead processed claims through a contracted insurance company. The commenter asked whether the on-site data processing reviews would be performed at the insurance company. If not, the commenter asked how the reviews would be conducted.

Response: In instances when the SCHIP claims are processed through an insurance company, the review contractor most likely will conduct the reviews on-site at the insurance company.

d. Difference Resolution

Comment: A commenter recommended that the review contractor be required to provide the State with all documentation it received for each claim rather than partial documentation. This will allow the State to adequately evaluate the review contractor's decision.

Response: We believe the determination of the level of information needed should be made on a case-by-case basis. The RC or the DDC, or both, will provide the State with sufficient information on which it can decide if it disagrees with the error finding. We believe that it is inefficient for the RC to provide the State with all documentation on every claim and, therefore, we are not adopting this recommendation.

Comment: Several commenters noted that the difference resolution process needs more specific information to be adequately evaluated. They said that it could be rendered ineffective if it excluded review differences under an arbitrary amount (for example, $100) and did not include all the information received by the review contractor. One commenter recommended eliminating the $100 dollar threshold in the dispute resolution process.

Response: We have restricted when States can appeal an error finding in order to prevent *de minimis* disputes and to ensure that appeals to CMS address only those claims that are substantial enough to warrant re-consideration. Therefore, we are not adopting this recommendation. The $100 threshold for appeals at the CMS level also ensures that States receive timely decisions on their appeals, which could be jeopardized if the CMS appeals process was inundated with appeals by every State on error findings with a dollar value of less than $100. This threshold is similar to Medicare's Comprehensive Error Rate Testing program's threshold, which allows contractors to dispute one error finding per quarter.

As always, if a State is aggrieved by the contractor's adjudication or CMS' reconsideration, or wants to address errors with dollar values of less than $100, it can appeal to the Departmental Appeals Board.

Comment: A commenter noted that no time limits or restrictions were placed on the difference resolution process. A State may find it difficult to adequately review cases without sufficient time, especially if the review contractor is behind in its review process.

Response: We plan to release guidance to States on the difference resolution process through our review contractor, which will include timeframes to respond to and resolve differences.

Comment: A commenter stated that the difference resolution process is cited as a means to resolve disputes between States and the review contractor. However, according to the commenter, it is unclear whether all differences can be addressed in this process. The commenter also stated that the difference resolution process does not outline a process that addresses what happens if there are still unresolved differences between States and the review contractor in the final report.

Response: All differences in the review contractor's error findings other than errors due to no documentation are addressed in the difference resolution process. We also stated that errors due to insufficient documentation will be excluded from consideration because the difference resolution process is not intended to provide an extended timeframe for submitting additional documentation. However, we believe there are instances when States should be allowed to dispute errors attributed to insufficient documentation. Therefore, at a minimum, States will be able to dispute ''insufficient documentation'' errors when the State contends that: (1) There was documentation in the case record at the time of the medical review which was overlooked or misinterpreted by the reviewer; or (2) the State's written policy in effect at the time the service was rendered did not require the specific documentation that was the basis for the initial error finding. (This provision excludes policies developed after the fiscal year under review and made effective retroactive to the date of service.) Operational details regarding the difference resolution process will be issued via CMS guidelines.

Comment: Assuming that the number of unresolved differences between the State and the review contractor will be very small, a commenter suggested that the unresolved differences be considered ''undetermined'' and not be included in error rate calculations.

Response: The contractor's reviews findings will stand for purposes of the error rate calculations in cases where the differences remain unresolved after the conclusion of the difference resolution process. After the State's error rate has been calculated for purposes of PAR reporting, a State may request a new error rate calculation from the statistical contractor based on resolution of outstanding differences when the expected impact of the change in the error rate is at least 0.25 percentage points. The state can use this recalculated error rate for its own purposes (for example, corrective action, analysis, budgetary and resource planning).

Comment: A commenter noted that formal procedures for resolving differences have not been published. The commenter observed that States should be given the opportunity to review and comment on the procedures before implementation to ensure that concerns raised by States in previous public comments are addressed.

Response: We will release formal guidance for resolving differences in the difference resolution process through the review contractor. We will take the concerns expressed by the States into consideration as we implement the difference resolution process.

Comment: A commenter stated that an error of less than $100 on a claim should not be considered an error, since these findings cannot be considered in the difference resolution process.

Response: The $100 threshold applies only to appeals to CMS. Error findings with a dollar value of less than $100 could be considered in the difference resolution process.

6. Payment Error Rate and Reporting

Comment: A commenter noted that OMB guidance M–03–13 stated that OMB defines ''significant erroneous payments'' as ''annual erroneous payments in the program exceeding

both 2.5 percent of program payments and $10 million.'' The commenter asked whether erroneous payments in PERM that fail to meet either threshold at the State level would not be reported and not be repayable to the Federal government.

Response: The above noted definition of ''significant erroneous payments'' was provided by OMB to help agencies identify programs that are susceptible to significant erroneous or improper payments for purposes of measurement under the IPIA (in this case the Medicaid and SCHIP programs). The criteria set forth in the definition of ''significant erroneous payments'' is not relevant to computation of the error rate or recoveries. They are only applicable to the Federal agencies.

Comment: A commenter asked CMS to define the term ''agency'' as that term is used in § 431.974(a)(2) of the August 28, 2006 interim final rule. The commenter indicated that some States have divisions and departments rather than agencies.

Response: The term ''agency'' is defined in § 431.958 of the August 28, 2006 interim final rule. Under that provision, the term is defined as follows: ''*Agency* means, for purposes of the PERM eligibility reviews and this regulation, the agency that performs the Medicaid and SCHIP eligibility determinations under PERM and excludes the State agency as also defined in the regulation.'' Under this definition, the term ''agency'' could mean a State's division or department as well. We use the word ''agency'' as a general term recognizing that States have various words. Therefore, States should apply the term ''agency'' appropriately to mean division or department.

C. Expanded FY 2007 Error Rate Measurement

1. Eligibility

a. Cost and Burden

Comment: A commenter stated that the August 28, 2006 interim final rule is a complete reversal of the policy that was established in the October 5, 2005 interim final rule, in that the cost and burden of the PERM eligibility reviews is placed back on the States instead of having the reviews administered by a national contractor.

Response: The October 5, 2005 interim final rule stated that, based on comments and recommendations on the August 27, 2004 proposed rule, we adopted the recommendation to use a CMS Federal contractor to estimate medical and data processing error rates for Medicaid and SCHIP based on reviews of adjudicated FFS and managed care claims. In that same interim final rule, we also noted that we would convene a workgroup that would consider the best approach to measure improper payments based on eligibility errors within the confines of current law and with minimal budgetary impact. In addition, we pointed out that States could be required to conduct at least part of the eligibility reviews, and that any additional requirements placed on States would be detailed in a subsequent issuance. Therefore, the requirements in the August 28, 2006 interim final rule obligating States to conduct the eligibility reviews is consistent with the stated intent in the October 5, 2005 interim final rule and with the August 27, 2004 proposed rule that required States to conduct the eligibility reviews. Both of those rules alerted States that they would likely have to conduct at least part of the eligibility reviews. As a result, we disagree that there has been a policy reversal on this matter.

Comment: Several commenters stated that the eligibility review requirement placed a significant staffing and financial burden on States. The commenters believed that since they did not have the funding available for additional personnel, they would have to shift staff away from other programs to comply with this requirement.

Response: Based on our plan to rotate States for the PERM measurement, States can plan for the eligibility reviews. Each State also has the option of contracting out the eligibility reviews to an entity that is not directly participating in the State's eligibility and enrollment processes for either program, which may lessen State burden. In addition, it should be noted that, depending on a State's most recent error rate established under PERM, the sample size for subsequent eligibility reviews needed to produce a reliable error rate could be reduced in future years, thus further reducing cost and burden. We are also considering other means to minimize cost and burden related to the eligibility reviews. To that extent, we are providing in this final rule a provision to eliminate duplication of the negative case action reviews under both the PERM and Medicaid Eligibility Quality Control (MEQC) programs. We will provide in this final rule that, in a year a State conducts the negative case action reviews under PERM, these PERM reviews will be considered to meet the negative case action requirements under MEQC.

Comment: A commenter believed that the rule would require experienced caseworkers to move into reviewer positions and deplete field offices of eligibility determination resources and thereby impact error rates in all programs (that is, Medicaid, Food Stamps, and Temporary Assistance for Needy Families) and place States at high risk of future Federal Food and Nutrition Service sanctions.

Response: The rule does not require experienced case workers to conduct the reviews. Furthermore, the annual active case sample size in a State's initial year under PERM is 504 cases per program. This annual sample size results in a State reviewing 42 cases per month per program. The annual sample size could be reduced in subsequent years based on the State's most recently calculated eligibility error rate under PERM. Therefore, we do not believe States will need to commit significant resources to the reviews, particularly to the extent that other programs would be negatively impacted.

Comment: Some commenters believe that the time and expense to conduct the eligibility reviews for approximately 1,000 cases (500 per program) is underestimated. Commenters stated that, even at the underestimated 108,800 hours for collection activities and 19,960 hours to complete the Medicaid and SCHIP reviews, this burden will have a substantial impact on States, especially smaller States.

Response: We believe the amounts which we provided in the August 28, 2006 interim final rule accurately estimated the impact on States. However, these amounts are estimates and we agree that States may experience higher or lower costs during actual implementation. It should be noted that States are reimbursed at the Federal Administrative Match Rate for these activities. We are considering ways to reduce costs through minimizing duplication of effort in the PERM and MEQC reviews or through other means.

Comment: Based on its experience with MEQC and the PERM pilot, a commenter stated that the estimates of the August 28, 2006 interim final rule are understated; according to the commenter, the estimates do not take the expanded scope of PERM into consideration.

Response: We considered estimates for the FFS, managed care and eligibility measurements for both Medicaid and SCHIP in the August 28, 2006 interim final rule as well as in this final rule. Insofar as this can be deemed to be an expansion of PERM, we did take that into account. However, we would not necessarily agree with the commenter that the interim final rule represents an expanded scope. Indeed, our decision to use national contractors for much of the

PERM measurement represents a narrowing of our scope. We believe that our estimates are accurate.

Comment: A commenter stated that CMS should further revise eligibility cost and burden estimates to reflect the need to hire and train staff, travel allotments, and the complexity of certain reviews that will require additional time to complete.

Response: We included an additional 2,135 hours in our estimates for supporting functions like training, supervision, quality assurance and creation of review tools, etc. The total 10,055 hour estimate represents the burden to complete review findings to show the disposition of each case and includes all of the review supporting functions.

Comment: A commenter believed that the burden estimates that CMS provided in the August 28, 2006 interim final rule do not adequately reflect the burden that States must assume in the PERM review process. The commenter stated that CMS should consider that, although the PERM cycle is 23 months, different staff will be required to complete different phases of each process. The commenter noted that the same staff will not be used for the FFS component, managed care component, and eligibility component.

Response: We estimated cost and burden for each function of the PERM program as outlined in the interim final rule. We refer to section V., Collection of Information Requirements of the August 28, 2006 interim final rule (71 FR 51077). We considered the cost of the staff in each individual function. We do not believe that additional costs necessarily will result from different staff working on different functions. We believe this will vary from state to state. We continue to believe our estimates are correct.

Comment: A commenter suggested that if PERM reviews cannot be used to satisfy MEQC requirements, then States should be reimbursed in full for the eligibility functions.

Response: In the August 28, 2006 interim final rule, we noted that States selected to conduct eligibility reviews will be reimbursed for those activities at the applicable administrative Federal match under Medicaid and SCHIP.

Comment: A commenter maintained that States that are preparing for or in the process of implementing a new Medicaid Management Information System (MMIS) or eligibility system should be exempt from selection until the implementation of the system has been finalized. Otherwise, the commenter stated that resources will be stretched to the maximum.

Response: We notified States of their selection in the rotation through a State Health Official letter released to all States on November 18, 2005. Therefore, we believe that States are able to adequately plan for the PERM measurement process and are not adopting this recommendation.

Comment: A commenter believed that there will be an increased cost to and burden on States if they choose to hire a consultant to perform eligibility reviews (for example, States would have to coordinate efforts to provide documentation to the consultant and manage the consultant).

Response: Contracting out the eligibility reviews to an outside vendor is an optional decision for States. If a State believes this option would have a detrimental effect, it is not required to select it.

Comment: A commenter stated that States should be allowed to conduct reviews in accordance with their eligibility policies, to reduce time and expense. According to the commenter and to further illustrate this point, the commenter indicates that States should not be required to document verification of income and age if the State's eligibility policy accepts self-declaration.

Response: The PERM eligibility reviews provide for a State to verify eligibility according to the State's policies to determine if the case meets the eligibility criteria set by the State. These instructions were developed to allow States to use their own policies to the maximum extent possible while ensuring a consistent methodology nationwide. We released instructions for conducting eligibility reviews through an October 10, 2006 State Health Official letter. These instructions provide for the acceptance of self-declaration under certain circumstances. These instructions are posted on our CMS PERM Web site at *http://www.cms.hhs.gov/perm/downloads/2007EligibilityGuidance.pdf.* The accompanying State Health Official Letter is posted on our CMS PERM Web site at *http://www.cms.hhs.gov/perm/downloads/2007ParticipationLetter.pdf.*

Comment: A commenter asked if reviewers would be required to accept a State's standards and processes and not verify information using other sources not used by the State.

Response: The eligibility instructions address sufficient evidence of documentation and also refer to section 7269 of the State Medicaid Manual for listings of acceptable documentation to verify eligibility for PERM purposes. We would expect reviewers to verify eligibility under the PERM reviews using these sources in cases where documentation is missing from the case record or is outdated and likely to change regardless of whether a State uses these sources to verify eligibility for the Medicaid and SCHIP program. However, since these documents (birth certificate, driver's license, etc.) are commonly used as evidence of eligibility, we would expect a State would already be using these sources.

Comment: A commenter stated that staff time devoted to developing a corrective action plan and reporting error rates must be considered in the review costs.

Response: We have considered these factors in our estimates. In the August 28, 2006 interim final rule, we estimated the cost and burden on States to be up to 1,000 hours per State per program to develop a corrective action plan and 9,980 hours per State per program to conduct the eligibility reviews and report error rates.

Comment: A commenter stated that PERM places a disproportionate and excessive burden on SCHIP by applying the same requirements to both Medicaid and SCHIP. The commenter stated that SCHIP is a significantly smaller program covering far fewer individuals than Medicaid and with a fraction of the expenditures of Medicaid. However, the smallest SCHIP programs will be required to sample the same number of cases at an estimated cost of $532,000 per program, which represents a significant amount of money for many SCHIP programs.

Response: From a sampling perspective, there is generally no difference between a small and large population. Specifically, a property of sampling is that, once the population size exceeds about 10,000, the population can be treated as if it were an infinite population. In other words, statistically speaking, beyond a universe of about 10,000, population differences do not have a significant effect on sample size. We have provided in our eligibility instructions that, based on the finite population correction factor, States with a SCHIP or Medicaid population of 10,000 or less can use a smaller sample size. After a State establishes its baseline eligibility error rate, it can use that rate to determine the sample size for the next measurement year, which could be smaller. Therefore, we expect that the State would experience a savings in cost and burden due to the smaller sample size.

Comment: Several commenters expressed concern that the eligibility reviews will significantly impact the SCHIP program's 10 percent cap on

administrative expenditures. Their comments include:

• PERM costs should be separate, as it was not part of the consideration when the cap was created. The costs will exceed the estimated costs of $400,000 under the regulatory impact statement. However, references to the SCHIP program in the analysis and response to public comments stated that there will be no consideration of exempting PERM activities from this cap.

• The estimated cost of $532,000 per program will have a particularly significant impact on smaller States, States which are close to reaching the 10 percent cap on administrative expenses, and which may exhaust their SCHIP allotments in the year that they must conduct PERM reviews. A number of States could be forced to serve fewer children and cut back on other important administrative functions, such as outreach, application processing, and quality improvement because of the new PERM requirements.

• States may exceed their 10 percent administrative cap and violate Social Security Act Title XXI since CMS noted, in the August 28, 2006 interim rule, ''We are not considering exempting the costs of PERM-related activities from the 10 percent cap on SCHIP administrative expenditures.''

Response: Although we respect the commenters' concerns that the eligibility reviews will significantly impact the SCHIP program's 10 percent cap on administrative expenditures, as we stated in the August 28, 2006 interim final rule, we view PERM as part of the cost of administering the SCHIP program.

Comment: Several commenters stated that they must obtain additional funds for additional budgetary issues (that is, hire and train staff, purchase materials, and modify and develop systems) through their biennial legislature. However, without specific guidance and particulars on PERM eligibility reviews, the requests for additional funds cannot be developed. CMS should finalize the PERM regulations and give States time to develop internal procedures and structure or consider deferring implementation or stagger the measurement of the programs.

Response: Our guidance for the eligibility measurement was released on October 10, 2006 and is posted on our CMS PERM Web site. We agree that the States selected for the FY 2007 measurement needed additional time to prepare for the reviews, and we provided these States with a 3-month implementation period. We believe the States being measured in FY 2008 and FY 2009 will have ample time to prepare for the reviews.

b. Eligibility Workgroup

Comment: A commenter stated that CMS should not implement the PERM eligibility reviews for SCHIP in FY 2007 as proposed in the August 28, 2006 interim final rule. Instead, the commenter recommends that CMS should convene a workgroup composed of all stakeholders—including Federal officials, State SCHIP directors and children's advocates—in order to develop an alternative methodology tailored more appropriately to the SCHIP program.

Response: The eligibility workgroup, which included both a State and a Federal SCHIP representative, carefully considered the impact the eligibility reviews would have on the SCHIP program when it developed its review methodology. During the process, the workgroup tailored its methodology to the SCHIP program (to the extent possible) while it took steps to maintain the consistency and integrity of the review measurement. As a result, we have implemented the PERM eligibility reviews for SCHIP in FY 2007 as proposed in the August 28, 2006 interim final rule. We also felt it was important to maintain consistency between Medicaid and SCHIP reviews to the extent possible to reduce burden on States whose SCHIP programs are Medicaid-expansion.

Comment: A commenter asked why no SCHIP representatives were invited to participate on the eligibility workgroup to comment on the eligibility sample size.

Response: We had one State and one Federal SCHIP representative on the workgroup. The sample size was determined by statistical measures that assumed a 5 percent error rate, since there are no reliable Medicaid eligibility error rates for the majority of States and no SCHIP eligibility error rates exist on which we could use as a basis to determine sample size. We have provided for a modest population correction, which could potentially reduce the sample size necessary for States with small Medicaid or SCHIP populations.

Comment: A commenter indicated that there were many States that participated in the PAM and PERM pilot projects. The commenter asked how the two States that participated in the eligibility workgroup were selected, and whether these States participated in the pilot projects. In addition, the commenter asked CMS to provide a schedule and meeting minutes that were held in developing the eligibility review methodology.

Response: We convened an eligibility workgroup comprised of DHHS (including CMS and, in an advisory capacity, the Office of the Inspector General (OIG)), OMB, and representatives from New York and New Jersey, as selected by the American Public Health Services Association. We did not believe that their previous participation in the PAM/PERM pilots was necessary since the purpose of the workgroup was to establish a methodology for eligibility reviews based on a case sample. The eligibility reviews conducted in the PAM/PERM pilots were based on a claims sample. We also developed the methodology based on the workgroup's consideration of public comments and the examination of various approaches proposed in these comments.

c. Duplication of Effort

Comment: Many commenters noted that the interim final rule requires States to conduct two eligibility reviews—once for the MEQC program and once for the PERM program. Commenters responded as follows:

• One State noted that the August 28, 2006 interim final rule prohibiting PERM reviews from being substituted for MEQC reviews conflicts with the information collection request and supporting statement that indicated this substitution would be possible. States need a final decision in order to plan for adequate staffing.

• Another commenter wanted to know whether the PERM review could substitute as a MEQC pilot program. A number of commenters urged us to reconsider allowing the option of substituting PERM eligibility reviews for MEQC eligibility reviews since the requirements for States to conduct both MEQC and PERM eligibility reviews is duplicative, administratively burdensome, and, a poor use of resources. If States use PERM reviews to substitute for MEQC reviews, the commenters asked whether the PERM review would preclude imposition of financial penalties that would otherwise apply to the standard MEQC program.

Response: The notice of information collection requirements, published in the **Federal Register** for public comment on July 22, 2005 (70 FR 42324), was in draft form for comment. We republished the final notice in the **Federal Register** on September 1, 2006 (71 FR 52079). We have determined that the PERM program is not intended to supplant other programs, such as the MEQC program. However, in an attempt to reduce duplication of effort, we have

decided that the negative cases reviews under PERM can be used to fulfill the negative case review requirements under MEQC at § 431.812 for the fiscal year a State is being measured under PERM. We will amend the MEQC regulations accordingly. Finally, any recoveries due to Medicaid eligibility errors that fall within the scope of the MEQC program would be recouped through the MEQC program at section 1903(u) of the Act and would be subject to the 3 percent disallowance. SCHIP improper payments identified through the PERM eligibility reviews are subject to recovery under section 2105(e) of the Social Security Act.

Comment: A commenter asked if States are allowed to substitute PERM reviews for MEQC reviews, whether MEQC staff could conduct SCHIP eligibility reviews in lieu of MEQC reviews, or whether States with SCHIP programs that are not Medicaid expansion programs would be required to hire separate staff for the SCHIP reviews.

Response: As noted above, States cannot substitute PERM reviews for the MEQC active case reviews. Furthermore, we wish to clarify that under PERM, SCHIP eligibility reviews include all cases where benefits are paid by title XXI funds, which would include Medicaid expansion cases. We are not requiring SCHIP programs to hire separate staff to conduct eligibility reviews under PERM; certain commenters have made this decision on their own. As previously stated, each State must determine and ensure that the agency and personnel that develop, direct, implement, and evaluate the PERM eligibility reviews and associated activities are functionally and physically separate from the State agencies and personnel that are responsible for Medicaid and SCHIP policy and operations.

Comment: A commenter asserted that the regulations conflict on whether MEQC reviews can be substituted for PERM reviews. The commenter noted that CMS presently mandates MEQC reviews. According to the commenter, States would experience a duplication of effort since these reviews would not be eliminated or replaced through the proposed regulation. The commenter stated that there are distinct and notable differences between the PERM and MEQC reviews.

Response: We cannot waive the MEQC statutory requirements and have determined that the PERM eligibility reviews will not be used to meet the MEQC requirements. We agree there are distinct and notable differences between the PERM and MEQC reviews. However, the PERM reviews were developed in response to the IPIA and were never intended to mirror MEQC reviews. Therefore, we do not believe the regulations conflict.

Comment: A commenter stated that consideration has not been given to waive PERM review requirements for States that have efforts underway to measure improper payments.

Response: PERM enables us to comply with the reporting requirements under IPIA. It is not intended to replace existing efforts by States independently to measure improper payments.

Comment: Several commenters recommended that regulatory changes be made to allow PERM reviews to substitute for MEQC reviews in years when States are selected for the PERM program and revert back to MEQC reviews in non-PERM years. The commenters stated that CMS has the authority to change the PERM methodology.

Response: We have previously stated that the PERM eligibility reviews were developed to comply with the IPIA and are not intended to substitute for other program initiatives. Therefore, we are not adopting this recommendation.

Comment: Instead of conducting simultaneous reviews for PERM and MEQC, one commenter made the following recommendations: (1) Waive the MEQC requirements for the PERM year; (2) during PERM measurement years, allow States to use the PERM quarterly samples for eligibility reviews; and (3) eliminate the stratification for eligibility and reduce the number of months data are collected to manage the aggregate sample size at the State level.

Response: As indicated earlier, we cannot waive MEQC since the program is a statutory mandate. In addition, the PERM quarterly FFS and managed care samples, which during the PAM/PERM pilots were the basis for the eligibility reviews, are claims-based. We determined through the PAM/PERM pilots that a claims-based sample was not conducive to eligibility reviews because the time lag between when the claim is paid and when the service was received (when eligibility is verified) could be up to two years. This time lag not only would make verifying eligibility expensive and difficult but also would not produce current information on which to base corrective actions. Finally, stratifying active cases ensures that the number of recently determined cases (applications and redeterminations) will be large. If the active cases were drawn randomly without stratification, most of the determinations would be months old, which would make verifying eligibility as of the State's last action difficult and expensive. The data are collected evenly over the entire year, rather than being concentrated in one or two months, to reduce the potential for biasing the eligibility error rate if there is seasonality in the errors.

Comment: A commenter pointed out that CMS has stated that it is ''considering'' methods to minimize duplication of efforts in eligibility reviews. However, States speculate this will not be addressed.

Response: We have identified one area in which we can reduce duplication of effort. In this final rule, we will amend the MEQC regulations at § 431.812 to provide that a State can use the PERM negative case action reviews to meet the MEQC requirements for negative case action reviews in the Fiscal Year a State is being measured under PERM.

d. SCHIP Concerns

Comment: A commenter stated that SCHIP programs are charged with examining the quality of services rendered through their programs and clearly demonstrating their ability to provide preventive services to the child population. The commenter indicated that the majority of SCHIP programs report this information in their annual reports to CMS. The commenter asked whether ''the model and leading edge'' for which SCHIP has become known will be curtailed or stopped as a result the PERM regulations. The commenter stated that, in 2007, it could spend 15.9 percent of its entire administrative budget on PERM-related activities. The commenter asked what would be lost if these activities forced States to exceed their financial cap on administrative federal funds.

Response: The PERM activities are not intended to curtail or impede other activities for SCHIP. Since States know when they will be selected to participate in PERM, we expect that States would be able to budget for the reviews in a manner that would not impede these other activities.

e. Administration of Eligibility Reviews

Comment: A commenter asked whether a SCHIP stand-alone State office would be excluded from performing eligibility reviews, even though it does not determine eligibility but does develop policies and procedures.

Response: We believe that an office that develops program policies and procedures and also conducts the PERM eligibility reviews most likely would not provide independence to the reviews and should be excluded. However, we

also believe that the States should have the flexibility to determine which agency performs the reviews based on our clarification of the requirement for a separate and independent agency (as provided on the CMS PERM Web site in the Q & A Section at *http://www.cms.hhs.gov/PERM/Downloads/PERMQ&A072507.pdf*).

Comment: Several commenters asked whether a State could contract with an appropriate vendor to conduct eligibility reviews or whether only another State agency could conduct the reviews.

Response: Yes, the State can contract with a vendor, as long as the contracting entity did not participate in the State's eligibility determinations and enrollment activities and does not report to and is not overseen by the State agency responsible for eligibility, policies and operations.

Comment: Several commenters did not support the requirement that PERM eligibility reviews must be functionally and physically separate and independent from the State agency responsible for Medicaid and SCHIP policy and operations, including eligibility determinations. They recommended that we remove the ''separate and independent'' requirement. One commenter believed it was administratively cumbersome and unnecessary to place the PERM reviews outside of its Department of Health and Human Services particularly because shifting responsibility to conduct eligibility reviews to agencies that do not have expertise in Medicaid and SCHIP will result in incorrect findings and misapplication of Federal policy. According to the commenters, the ''separate and independent'' requirement could also limit State flexibility and unnecessarily increase the complexity and cost of PERM administration. The commenters also believed that States would have difficulty securing contracts without sufficient time.

Response: We agree that the States selected for the FY 2007 measurement might not have adequate time to secure contracts, and we apologize for the short notice of this option. However, all States have adequate time to secure contracts for future years if they wish to elect this option.

The intent of the requirement to have the agency responsible for the PERM eligibility reviews be physically and functionally separate from the State agency responsible for program policies, operations, and eligibility determinations is to ensure a level of independence and integrity in the review process. We do not believe that having these staff commingled or having one supervisor immediately responsible for both functions provides this assurance. Therefore, we are not adopting this recommendation. However, we are clarifying in this response that this requirement does not preclude the State from placing the agency responsible for the PERM eligibility reviews within the same single State agency or umbrella agency as the State agency responsible for program eligibility policies and determinations, provided that both agencies do not report to the same immediate supervisor—for example, first-line manager, Unit, Branch or Division Director. Our standard is that the agency responsible for the PERM eligibility measurement report to upper management that does not have direct responsibility for program policies, operations and eligibility determinations. We also strongly recommend that this agency also have a direct reporting line to the head of the single State agency or other top management—that is, the State Medicaid Director, State SCHIP Director, and Commissioner or equivalent thereof. States should arrange the placement of the PERM eligibility measurement to achieve this standard to the extent possible.

Comment: Several commenters believed that State employees who were not physically and functionally separate from the State agency responsible for eligibility policy and operations were currently performing MEQC activities. The commenters stated that there was no evidence to support that the current organizational structure presented a conflict of interest for MEQC. In addition, they maintained that there was no indication that the program integrity process could be compromised by the location of employees conducting the reviews. The commenters believed that placing restrictions on State resources used to comply with PERM eligibility requirements would increase the complexity and cost of administration.

Response: It is important to note that the MEQC program and the PERM eligibility measurement are separate and distinct requirements and should not be compared. However, regarding the placement of MEQC staff, the State Medicaid Manual, Part 7, section 7005 provides guidance on administering the MEQC program and specifically states that MEQC staff should report to top management, and that the State should ''separate staff physically and functionally from operating units and policy units.'' The Manual states that any other organizational structure requires CMS regional office concurrence. In addition, section 7218 of the Manual further discusses the independence of the MEQC review. The similar requirement for the PERM eligibility reviews was adopted from a recommendation made through public comment on the October 5, 2005 interim final rule because we believe it helps to ensure the integrity of the reviews. Therefore, we believe the PERM requirement is appropriate and, for those comparing the programs, is consistent with the requirement for the independence of the MEQC reviews as expressly stated in the State Medicaid Manual.

Comment: A commenter stated that it contacted CMS on whether its structure would meet the regulatory requirement to have the agency conducting the PERM eligibility reviews be functionally and physically separate from the State agency responsible for Medicaid and SCHIP eligibility policy, operations, and determinations. This commenter explained that its Program Integrity division, which conducts QC reviews, is within the Medicaid Agency and is separate and independent of its Eligibility Division that is responsible for setting policy and determining eligibility. The commenter requested a clear and definitive answer of whether or not its Program Integrity Unit can conduct the eligibility review.

Response: Section 431.974 in the August 28, 2006 interim final rule outlines the basic elements of Medicaid and SCHIP eligibility reviews, including the parameters for determining which agency can perform the reviews. We provided further interpretation of these provisions in eligibility instructions through an October 10, 2006 State Health Official Letter and the CMS PERM Web site at *http://www.cms.hhs.gov/PERM*.

We are also clarifying this specific requirement in this final rule. As a result, we believe that States should have sufficient guidance on which to determine which agency within the State's organization should appropriately conduct the reviews. We are not approving each State's determination, as the commenter urges us to do in this case, that the agency assigned to perform the reviews or that the State's organizational structure meets the regulatory requirement in § 431.974(2) of the August 28, 2006 interim final rule. That determination is reserved for each State to make. In this particular situation presented by the commenter, although we do not know the State's organizational structure, based on the description we believe that, as long as the Program Integrity Unit does not report to the same

immediate supervisor as the Eligibility Division, and reports to upper management and, preferably, has direct reporting to the State Medicaid or SCHIP Director or other top management, the placement of the PERM eligibility reviews within the Program Integrity Unit appears reasonable.

Comment: Two commenters stated that the regulation needs further clarification so that States can determine which unit or agency can perform the PERM reviews.

Response: To assist States to determine which agency can perform the PERM eligibility reviews, States should determine:

- Whether the PERM review (eligibility and payment) staff would be physically separate from the program eligibility review staff, for example, located on a separate floor in a building or located in a separate building and not commingled in any way.
- Whether the eligibility review agency would be functionally separate and independent from the agency responsible for eligibility determinations, policy and operations. The PERM unit should not report to the same agency head, first line supervisor, Division Director or other immediate supervisor. There should be at least one level of supervision between the agencies and upper management. For example, each agency would report to its own immediate supervisor; both supervisors would then report to upper management. We recommend that the PERM agency also have a direct reporting line to top management, for example, State Medicaid Director or Deputy Commissioner.

Comment: A commenter was concerned with the agency conducting the PERM reviews being a part of the same Medicaid office or division, not the same State agency.

Response: We have clarified in this final rule that the agency conducting the PERM reviews can be housed within the same State agency containing the program office or division. However, this agency should not be housed in the same office or division as the State agency responsible for eligibility to the extent that both agencies are commingled and report to the same immediate supervisor, for example, a first-line manager or Division Director, because we do not believe this placement would support the independence of the reviews and the findings.

Comment: A commenter noted that the requirement that the agency conducting the PERM eligibility reviews be functionally and physically separate from the State agency responsible for Medicaid and SCHIP policy operations poses a considerable hardship on the State and requires creating a completely new entity or organizational structure within the State. CMS should allow States to use the agency that is most familiar with eligibility requirements to conduct the PERM eligibility reviews.

Response: We are not requiring States to create a new entity or organizational structure. Rather, we expect States to place the PERM eligibility reviews within the States' organizational structures in a manner that provides integrity and independence to the reviews and in accordance with our clarifications provided above.

Comment: A commenter stated that the functional and physical separation requirement contradicts CMS' assertion that having the State conduct the eligibility review will reduce or eliminate the demand that would otherwise be placed on State staff to educate a contractor about eligibility issues. The current staff will have to take time to provide technical assistance to the PERM audit staff that the State would need to establish under this requirement, thus increasing the cost of conducting these reviews.

Response: Providing technical assistance to State staff rather than the Federal contractor would not necessarily increase the cost of conducting the reviews. State policies by which reviews are conducted are already in-house. In addition, States can determine the appropriate agency to conduct the reviews or contract out this function, either of which may not require extensive technical assistance.

Comment: A commenter asked whether it is CMS' intent that States hire staff dedicated solely to PERM.

Response: No States should decide which staff are appropriate to implement the eligibility methodology under PERM within the parameters required by this regulation.

Comment: A commenter asked if States choose to hire staff for the PERM project in years they are measured, what functions would this staff have during the off years when the State is not being measured.

Response: It is not our intent to require States to hire staff dedicated solely to PERM. However, States have the discretion to hire such staff if they wish to do so.

Comment: A commenter stated that the requirement seems to contradict a response to a comment made at a conference regarding the difficulty of staffing for PERM when staff is only needed every three years. The CMS oral response suggested using eligibility reviewers on an interim basis between PERM selection years to enhance Medicaid or SCHIP program integrity activities, which suggests that CMS would want States to use these employees to staff ongoing operations in the agency.

Response: We responded to a similar comment in the August 28, 2006 interim final rule in which we stated that, with respect to eligibility reviews, staff for PERM would be needed longer than one year because the process to measure one fiscal year takes approximately 23 months. In the time period before a State's next PERM measurement activities (approximately 13 months), we suggested, in response to the oral comment, that a State could use the staff for other quality assurance initiatives, such as enhancing its MEQC and SCHIP program integrity activities. We were not suggesting that PERM employees staff ongoing agency operations. This response, as well as the oral response at the conference, was intended to clarify that staffing is not necessarily needed for only 1 year, there are other areas where staff could be used when not needed for PERM activities. However, we do not necessarily expect States to hire staff devoted to PERM. We have provided States the option to contract these reviews out to an entity not actively involved with the State's eligibility and enrollment activities.

Comment: A commenter asked if CMS will allow MEQC staff to perform the PERM review to satisfy the requirement for the MEQC program.

Response: No. States that would use the MEQC staff to perform the PERM review would necessarily need to reduce MEQC activities or scope of reviews to divert MEQC staff to conduct the PERM reviews.

Comment: A commenter recommended allowing States the option to use MEQC staff to perform PERM eligibility reviews.

Response: We are not adopting this recommendation because we do not agree that the current level of effort committed to the MEQC program should be reduced to accommodate the PERM eligibility reviews.

Comment: A commenter asserted that this provision would require States to contract out the eligibility reviews, because no other State agency would have the expertise to perform the reviews. Contracting out eligibility reviews would result in duplication of organization and add significantly more costs.

Response: We have given States the discretion to organize their eligibility review staff as they see fit within specific parameters. Our clarification of

this provision provides States flexibility to place the PERM reviews in the appropriate agency as well as contracting with an external organization.

Comment: Several commenters asked if it was CMS' intent for the State agency to contract with an outside vendor to conduct the PERM eligibility reviews. If so, then the eligibility component of PERM should be delayed to allow time for the States to develop and implement contractual arrangements.

Response: It was not our intent to require a State agency to contract with an outside vendor to conduct the PERM eligibilities reviews. However, this approach is an option a State may wish to pursue.

f. Review Methodology

Comment: A commenter stated that the interim final rule provided little specific guidance as to the processes and methodologies that should be employed for conducting the eligibility reviews, thereby making it difficult to develop a sampling plan and determine complete staffing and financial needs to conduct the reviews.

Response: We released detailed eligibility review instructions to the States being measured in FY 2007 through an October 10, 2006 State Health Official Letter. These instructions are posted on our CMS PERM Web site at *http://www.cms.hhs.gov/perm/downloads/2007EligibilityGuidance.pdf.* The State Health Official Letter is posted on our CMS PERM Web site at *http://www.cms.hhs.gov/perm/downloads/2007ParticipationLetter.pdf.* States may access these Web sites to obtain this information.

Comment: Several commenters stated that the regulations do not contain any specifics on conducting the eligibility reviews. Their comments include:

- CMS is preparing more detailed instruction about PERM without public comment or input. CMS should make the policy for eligibility reviews available to all States, not just States selected for the FY 2007 reviews, as soon as it is available to allow sufficient time to set up procedures and train staff accordingly.
- CMS should clarify in its instructions that PERM reviewers are not required to consult information sources other than those that the State itself had to consult in making the underlying determination. Therefore, if a State's verification and other procedural requirements comply with Federal law and the eligibility caseworker complied with State procedures, PERM reviewers should not be required to independently verify information upon which the State's determination was made. Otherwise, the estimated errors will be overstated, which may compel States to implement more restrictive procedural requirements and thereby resurrect barriers to the enrollment of eligible individuals.

Response: We announced in the October 5, 2005 interim final rule our intentions to establish an eligibility workgroup to make recommendations on the best approach for reviewing Medicaid and SCHIP eligibility within the confines of current statute, with minimal impact on both States and on additional discretionary funding. We convened an eligibility workgroup, which included representatives from two States, and we considered public comments. In the August 28, 2006 interim final rule, we published our eligibility review methodology and invited further public comment. In addition, as noted, we have made our eligibility review instructions available to all States, not just to States that were selected for FY 2007 reviews, on our CMS PERM Web site at *http://www.cms.hhs.gov/PERM.*

Finally, we do not agree with the commenter's statement that, if a State's verification and other procedural requirements comply with Federal law and the eligibility caseworker complied with State procedures, PERM reviewers should not be required independently to verify information upon which the State's determination was made. The purpose of the eligibility review is to verify that the individual is actually eligible for the program, not to verify that the State's policies comply with Federal law or to determine that the caseworker conducted the review appropriately. Therefore, in some instances, the PERM review may necessarily go beyond the State's procedures and caseworker's actions to verify eligibility.

Comment: Some commenters recommended postponing the commencement of the eligibility review component. The comments included:

- States cannot develop sampling plans that meet CMS expectations due to the uncertainty of expectations.
- States must follow budgetary processes to get necessary State agency or contract staff and may not have adequate time to arrange funding.
- States need additional guidance as to the sampling processes and methodologies for reviewing cases, as well as time to arrange the necessary infrastructure and funding needed to support the eligibility review.

Response: In the October 5, 2005 interim final rule, we announced the States selected for Medicaid FFS, managed care, and eligibility reviews in FY 2006, FY 2007 and FY 2008, so that the States would know in advance in which year they will be measured under PERM. We also stated in that rule we expected the determination of the eligibility error rate would require State participation, and that we planned to have the eligibility reviews commence in FY 2007. Finally, we notified all States in an August 30, 2006 State Health Official Letter that States will conduct the eligibility reviews, and we met with States at two conferences held in September 2006 to provide additional information. Therefore, we believe States had preliminary information to help prepare for conducting the required eligibility reviews, which were followed up with detailed written eligibility review instructions released on October 10, 2006. Finally, the FY 2007 States, which had less advance notice than the remaining States, are already working successfully with our contractors in developing their sampling plans. Therefore, we are not adopting the recommendation to delay implementing the eligibility reviews.

Comment: A commenter suggested that CMS clarify that PERM reviews will not immediately encompass State compliance with significant changes in Federal rules or policies until States have had a reasonable opportunity to implement the new rules.

Response: The PERM reviews will follow State policies and procedures so long as they comply with Federal requirements, using the effective dates of the Federal requirements and CMS policies regarding State implementation. The PERM reviews are not intended to hold States harmless in matters of non-compliance. Therefore, we are not adopting this recommendation.

Comment: A commenter recommended that the FY 2007 PERM reviews should not encompass the Medicaid citizenship documentation requirements, which went into effect July 1, 2006 under the Deficit Reduction Act of 2005. The commenter believed that since CMS policy in implementing the new documentation requirements has not been completely settled in a final rule, the uncertain nature of the new rules will make it difficult for States to be in full compliance in FY 2007.

Response: The PERM review of citizenship for Medicaid will follow CMS policy set out in a final regulation with comment published on July 12, 2006 (71 FR 39214) and any subsequent regulatory and policy guidance.

For purposes of the PERM reviews, if documentation is missing from the file that should have been obtained under this final rule with comment, the reviewer would need to make a reasonable attempt to obtain evidence of citizenship either independently or through beneficiary contact.

Comment: A commenter noted that the PERM eligibility sampling and stratification requirements will require complex system coding and is a radical departure from traditional MEQC sampling techniques. The commenter recommended that CMS consider suspending MEQC reviews during the PERM review year.

Response: The PERM eligibility reviews are independent of MEQC, and their methodology should not be compared to MEQC. As stated in the August 28, 2006 interim final rule, the PERM program is intended to fulfill the requirements of the IPIA and is not intended to substitute for other program integrity activities in which the States are currently engaged. In addition, the MEQC program is a statutory requirement, so we cannot suspend it during the year a State is measured under PERM. However, as previously stated, we are considering how we can reduce duplication of efforts and have addressed the negative case reviews required under both the PERM and MEQC programs.

Regarding stratification of the universe, we agree that some States may face challenges in identifying cases for appropriate placement in each stratum. However, the stratification allows for reviews of an equal number of (a) Applications (that is, initial determinations); (b) redeterminations; and (c) all other cases; and provides administrative ease in the review of cases in strata (1) and (2), since the State's most recent action will have occurred within one to two months of the sample month. (The most recent action for cases in stratum (3) may have occurred up to twelve months prior to the sample month.)

If we did not stratify the universe in this manner, States would incur additional cost and burden associated with verifying eligibility for all cases in the sample at up to twelve months prior to the sample month. The result could be an increased number of cases where eligibility could not be determined as well as a loss of information on error causes that is both timely and specific to applications and redeterminations on which a State can base corrective actions.

Comment: A commenter argued that basing the sampling process upon individual recipients, rather than on cases, adds complexity to the anticipated programming time and costs.

Response: Sampling by individuals rather than by cases was a State recommendation, through public comment, that we adopted. We recognize that all State Medicaid and SCHIP programs are unique, and that sampling by individuals would not accommodate all States. However, in order to have a consistent approach to the eligibility measurement, one approach to sampling and review is necessary.

Comment: A commenter stated that there is not a clear schedule to pull eligibility samples and begin reviews. The commenter stated that if such work is implemented without sufficient time, then an unrealistic expectation will be put on the States.

Response: The instructions posted on the CMS PERM Web site include a timeline that details the entire review process for FY 2007 (which allows these States a 3-month implementation period due to the short notice). The timeline will be revised and posted to the CMS PERM Web site prior to the beginning of FY 2008 to reflect sampling over a full year beginning in FY 2008. This can be found at *http://www.cms.hhs.gov/PERM.*

Comment: A commenter stated that, as demonstrated in the PERM pilot, unexpected changes, which impact eligibility, do occur after eligibility has been confirmed. Therefore, according to the commenter, the administrative period is applicable if States are required to determine the accuracy of eligibility determinations based on actual case circumstances in the review month.

Response: The PERM eligibility review verifies eligibility as of the State's most recent action on the case. Therefore, changes after the State's last action are not within the scope of the reviews, so the administrative period would not apply.

Comment: A commenter asks whether the States or CMS' statistical contractor will determine the number of eligibility reviews required to achieve the desired precision level.

Response: For FY 2007, FY 2008, and FY 2009, the statistical contractor has determined the sample size for the eligibility reviews. Future sample sizes will be set by the statistical contractor and will be based on the size of the variance from the State's previous error rate estimate under PERM. The State will have the opportunity to comment and recommend an alternative sample size, if appropriate.

Comment: A commenter asked whether CMS could provide specific information about eligibility review verification requirements.

Response: This information is included in our instructions, which are posted on the CMS PERM Web site at *http://www.cms.hhs.gov/PERM.*

Comment: A commenter asked whether States would be required to review the eligibility of all beneficiaries within a case, or would eligibility be reviewed for one selected individual beneficiary within a case.

Response: States are required to review eligibility for one beneficiary. If a State cannot identify individuals without requiring major system changes, it should demonstrate in its sampling plan how it will randomly select one person from the case sampled.

Comment: A commenter asked, since the interim regulation states that Medicaid and SCHIP are measured separately, whether CMS would recommend a way to review eligibility when it is determined for both Medicaid and SCHIP within an integrated eligibility system and a request for health care coverage is considered an application for Medicaid or SCHIP.

Response: A State would need to identify the Medicaid-approved cases for the Medicaid universe and the SCHIP-approved cases for the SCHIP universe and review the cases accordingly. For the negative reviews, if the application is denied for one or both programs, the case would be reviewed under both programs, or alternatively, under the one program for which eligibility was denied to ensure the denial was correct.

Comment: A commenter asked if CMS is going to provide States with an eligibility data collection system to ensure uniformity in the error rate calculation.

Response: States are responsible for the eligibility data collection, which will be submitted on CMS-provided forms for reporting purposes. We will provide a State with an error rate calculator to calculate the rate at the State's request.

Comment: One State recommends that a footnote be included in State reports when a SCHIP participant is found eligible for Medicaid but must be reported as ineligible for both programs.

Response: If a SCHIP case is found eligible for Medicaid but ineligible for SCHIP, it would not be reported as ineligible for both programs. Therefore, we are not adopting this recommendation.

Comment: According to a commenter, to exclude cases denied or terminated for failing to complete the application or

re-determination process eliminates valuable insight into a certifying agency's case processing practices and complaint resolution process.

Response: We agree. The decision to exclude these cases came from the eligibility workgroup. Panel members felt that States should be measured on the eligibility determinations that were based on complete information and participation by the beneficiary. However, there could be instances where a case should be properly included in the universe, for example, the beneficiary provided requested information but the State failed to act on the information and denied or terminated eligibility. Since a State's system most likely would not be able to make the distinction between these types of cases (or similar case situations) that should be included in the universe and other cases, that is, where the beneficiary did not provide information, we are adopting this recommendation to eliminate the exclusion of any cases in the negative universe and in the sample of redetermination cases.

Comment: A commenter requested that the procedure to exclude from the negative case universe cases that were denied or terminated based upon incomplete applications or cases where beneficiaries did not complete the redetermination process be clarified and that examples be provided for compiling the negative case universe for sample selection for eligibility reviews.

Response: We are adopting the comment not to exclude these cases from the negative case action universe. Therefore, these cases will be included in the compilation of the universe for sample selection purposes.

Comment: A commenter stated that § 431.978(d)(1)(i) excludes cases in which the Social Security Administration, under a 1634 agreement, determines eligibility for Supplemental Security Income (SSI) recipients. The commenter asked what the State should use to review determinations of Medicaid eligibility for SSI recipients in 209(b) States.

Response: Beneficiaries have to apply separately for Medicaid in 209(b) States because these States have one or more eligibility criteria more restrictive than SSI. Therefore, there is no link by law to the receipt of SSI cash and eligibility for Medicaid. States must conduct an eligibility review of this population just like they would for any other case where cash assistance does not convey automatic Medicaid eligibility.

g. Sampling

Comment: A commenter questioned CMS' remarks about producing State level error rates that meet 3 percent precision at a 95 percent confidence level given that the largest of States will have the same sample size requirements as the smallest State. The commenter recommended that States be allowed to draw samples that accurately reflect their unique Medicaid and SCHIP populations.

Response: The sample size chosen is estimated to obtain a precision level of 3 percentage points at the 95 percent confidence level, assuming an eligibility error rate of 5 percent (as decided upon by the eligibility workgroup).

By the nature of sampling, a sample size of 504 is likely to achieve the precision goal with a high probability. Once a State has an eligibility error rate under the PERM program, the State can use that rate to estimate the sample size needed to achieve the confidence and precision levels for the subsequent measurement. Therefore, we are not adopting this recommendation.

Comment: A commenter asked CMS to clarify and further define the sampling parameters (that is, confidence interval, confidence level, and margin of error) States are expected to use for active and negative cases to select the monthly samples.

Response: The details for sample parameters are discussed in our eligibility instructions that are posted on the CMS PERM Web site at *http://www.cms.hhs.gov/PERM.* In addition, our statistical contractor is available to discuss State-specific sampling plan questions.

Comment: A commenter stated that clear guidance is needed as to what States should do in estimating the margin of error for the sample size. The commenter asks whether CMS will allow States to set their own margin of error in the eligibility sampling plans.

Response: States should not set their own margin of error in the eligibility sampling plans but rather should follow the eligibility guidance on this matter.

Comment: Two commenters stated that the sizes of the universe and each stratum will cause an excessive burden on States. One of the commenters stated that CMS' decision to increase the eligibility sample size to produce an equal sample size per stratum does not consider the States' limited resources and fiscal constraints. The other commenter asserts that stratification will lead to a larger sample size, thus creating an excessive burden on the States.

Response: We have estimated the cost and burden for States to sample and review an annual sample size of 504 cases, which are evenly placed into the three strata. The sample size is based on an assumed 5 percent error rate and was not increased to produce an equal number of cases per stratum. We have provided for the finite population and that sample sizes may be reduced in future years based on a State's most recently calculated error rate. Therefore, we do not believe the requirement for States to annually sample and review 504 cases will cause an excessive burden on States.

Comment: A commenter stated that the positive sample size among participating States to meet PERM statistical requirements is understated. Given that the universe size influences the sample size, a State could have a sample size much larger than 201 cases per year. In addition, the commenter said that CMS cannot properly estimate cost and burden to States with sample sizes higher than 501 because CMS will not have sufficient information before the November 15, 2006 submission date for PERM sampling plans.

Response: The commenter is correct that there has not yet accumulated sufficient information to determine how sample sizes may vary across the states. For this reason, we made assumptions, informed by a working group consisting of representatives of several States, for the calculation of sample sizes.

In the initial year of implementation, the States are asked to use the sample sizes specified in the instruction for FY 2007. These sample sizes are 504 cases for active cases and 204 cases for negative cases. If the State had a very small caseload, it could include a finite population adjustment to these sample sizes in its sampling plan.

These sample sizes should be adequate if the assumptions used are accurate. Going forward, as evidence accumulates within individual States regarding the variation in eligibility error rates, the sample sizes may become more tailored to each State's respective circumstances.

Comment: Several commenters stated that CMS has not addressed the validity of the eligibility sampling approach. One commenter asked whether there will be weighting to balance the proportions of the three strata. The commenter stated that the stratification approach poses some methodology issues because the same case may be sampled more than once during the Federal Fiscal Year under review.

Response: There will be weighting to balance the proportions of the three strata. Equal sample sizes are drawn from each of the three strata, but the number of cases in the universe of each stratum will differ. Sampling weights must be applied to obtain the correct eligibility error rate for the complete

universe. The sampled cases and associated payments will be weighted by the inverse of the sampling frequencies with the three strata. This will ensure that the results within the stratum are appropriately weighted across the three strata to reflect the universe of all cases.

We are aware that the stratification approach poses some methodology issues. We have addressed how to review cases sampled more than once in a year in our eligibility instructions.

Comment: A commenter stated that, to prevent oversampling and, thereby reduce costs for States being measured under PERM, sampling should stop once the desired precision and confidence level are reached. The commenter noted that the sample size of 1,000 FFS claims is likely excessive for many States. In addition, the commenter stated that this final rule should state whether attribute and/or variable sampling will be performed.

Response: A goal of the sampling method is that all claims or line items have a positive probability of being sampled. This means that we cannot stop during the fiscal year when a desired level of precision is reached, because claims paid later in the fiscal year may not have a chance to be sampled. That said, if we find that a sample size of 1,000 produces precision levels in excess of those required, the sample sizes will be adjusted in subsequent years. Sampling for FY 2007 will be based on dollar value stratification, a form of attribute sampling.

Comment: A commenter noted that the August 28, 2006 interim final rule indicated that the total estimated annual sample size for Medicaid and SCHIP cases in the active universe is 501 cases per program per State. The commenter observed that formulas for both payment and case error rates were issued in that rule. The commenter asked which formula States should use to meet the statistical criteria. The commenter stated that the sample size used to obtain the desired precision will be different depending on the error rate used and may further be different in each stratum.

Response: The sample size estimate for the active case error rate, which is dollar weighted, is the following. It is taken directly from the instructions: *Payment Error Rate Measurement Verifying Eligibility for Medicaid and SCHIP Benefits FY 2007,* which are on the CMS PERM Web site at *http://www.cms.hhs.gov/PERM.*

Comment: A commenter stated that to accomplish the stratified sample of active cases consisting of one-third new determinations, one-third redeterminations, and one-third ongoing cases, a State would presumably have to estimate the annual number of opening and redetermination actions; calculate an interval; compile the information for each month and draw samples. Thus, the programming for stratified sampling will present some difficult and costly challenges and will impact other State program initiatives.

Response: To stratify cases, the State would identify all cases in the universe that are active in the sampling month. Based on the date of the State's last action and our definitions of cases for each stratum, the State would stratify the cases into the three strata. Next, the State would count the number of cases in each stratum. The State would not have to estimate the number; it would be an actual count. Then, if systematic sampling were used to draw the sample, a skip factor would be developed for each stratum, and, for FY 2007, 18 cases would be sampled a month from each stratum for the first 3 months and 19 cases a month for the last 6 months. The skip factor would be equal to the number in the universe in that stratum divided by sample size, which in this case would be 18. Alternatively, the State could draw 18 cases from each stratum randomly using a random number generator, selecting cases randomly after appropriately numbering the cases.

D. State Requirements

1. State Cost and Burden

a. SCHIP

Comment: Several commenters believed that PERM-related SCHIP activity costs should be 100 percent federally-funded to alleviate the burden on the State costs, resources, and extensive time necessary to support the Federal initiative.

Response: As we stated in the August 28, 2006 interim final rule, our adoption of the recommendation to engage Federal contractors to estimate the FFS and managed care components of Medicaid and SCHIP should reduce the cost and burden that States would have otherwise incurred to conduct medical and data processing reviews on these claims. We further reduced State burden by rotating States on a 3-year cycle, so that States will not incur an annual burden. In that same interim final rule, we noted that States selected to conduct eligibility reviews will be reimbursed for those activities at the applicable administrative Federal match under Medicaid and SCHIP. Finally, in the August 28, 2006 interim final rule, we evaluated and determined that the burden and cost of these responsibilities will not significantly impact the States.

b. Accuracy of Estimates

Comment: A commenter stated that the State cost estimate ($42,348 per program) for furnishing claims information to the Federal contractors is actually higher than estimated because it excludes costs associated with training and technical assistance.

Response: We do not believe that States will incur significant costs in providing such assistance. As stated in the August 28, 2006 interim final rule, we have engaged, and will continue to engage, a review contractor that has demonstrated knowledge and experience with claims reviews. In this way, we have tried to minimize the burden on States and ensure the accuracy of the reviews.

Comment: A commenter stated that, because sections of the interim rule remain unclear, the proposed burden estimates should be revisited when the issues are resolved.

Response: We have revisited the estimates as part of developing this final rule and continue to believe our estimates stated in the interim final rule are reasonable.

Comment: A commenter recommended that States should track their own PERM costs.

Response: States have the option to track their own costs for PERM for planning resources for upcoming years. However, tracking State costs is not required under this rule.

Comment: Two commenters asserted that the cost to the States is grossly underestimated. The commenters stated that the final cost estimate for Medicaid FFS, SCHIP FFS, and managed care reviews is for information collection purposes only. The commenters believed that State activities necessary to comply with CMS directives and to communicate with the national contractors are not accounted for in the estimates. According to the commenters, cost estimates were ignored for the following activities: corrective actions plans, provider education, difference resolution process, and technical assistance.

Response: Most of the cost estimates that the commenter notes were considered. In the August 28, 2006 interim final rule, we included the estimate for the costs of providing information for managed care, conducting eligibility reviews, and developing a corrective action plan. (We believe that the costs of monitoring and evaluating the corrective action plan are part of the States' overall operating procedures and, therefore, we did not

include these costs in our estimates). Estimates of this burden and these costs are indicated in section VI of that interim final rule. We estimated that it would take each selected State up to 500 hours for the FFS component, up to 500 hours for the managed care component, and up to 1,000 hours for the eligibility component of the corrective action plan for each program. Therefore, we estimate that the total annual burden associated with this requirement for 34 programs (Medicaid and SCHIP in 17 States) will be 68,000 hours (2,000 hours per State per program). It should be noted that cost estimates for provider education are included in the corrective action plans.

Cost estimates for the difference resolution process were also estimated. In the August 28, 2006 interim final rule, we stated that the selected States would have the option to enter the difference resolution process, and that States wishing to do so would have to notify the Federal contractor and submit documentation to support its determination that the claim was incorrectly paid. In that same interim final rule, we stated that the burden associated with this requirement would be the time and effort it would take for a State to gather the facts and valid documentation and submit it to the Federal contractor or, upon appeal, to CMS. We anticipate that 17 States (per program for a total of 34 programs) will request difference resolutions for each fiscal year, and that it will take up to 5 hours per claim to request a difference resolution and present evidence to support the State's disagreement with the Federal contractor's determination.

Finally, as stated in the August 28, 2006 interim final rule, we acknowledge that States must provide technical assistance to assist the RC in conducting the medical and data processing reviews (for example, a State may need to explain or clarify unusual policies or procedures and provide training on its MMIS or claims processing system). However, we believe this assistance provided to the contractor will not result in additional costs and estimate that the burden will be minimal.

Comment: A commenter stated that burdens related to State finances and staff resources are exacerbated because each State will deal with 3 contractors in coordinating information and training.

Response: We believe that our adoption of the recommendation to engage Federal contractors has significantly reduced the cost and burden to States. As stated in the August 28, 2006 interim final rule, States will be required to provide technical assistance—not training—on State policies only to the RC, who will examine State policies and the medical records to determine if payment for a FFS claim was medically necessary and paid correctly. States will also provide technical assistance to the RC on the data processing reviews of FFS and managed care claims.

2. Contacts with States

Comment: A commenter proposed that CMS initiate monthly conference calls with States, PERM contractors and sub-contractors to address ongoing PERM concerns and questions.

Response: We are adopting this recommendation and will establish the PERM Technical Advisory Group, which will hold conference calls with States, CMS, and, as appropriate, its contractors as a forum to address ongoing PERM concerns and questions.

3. Corrective Action Plans

Comment: A commenter stated that the interim regulation does not identify the requirements of the corrective action plan.

Response: We detailed the requirements in the preamble of the August 28, 2006 interim final regulation. See 71 FR 51071.

Comment: A commenter asserted that the States' concerns about the costs and resources associated with complying with the requirements of corrective action plans were ignored. The commenter also stated that CMS's intention for corrective action plans to be carried out within the restriction of the ongoing program seems to conflict with the States' goal to reduce improper payments.

Response: In the August 28, 2006 interim final rule, in response to concerns expressed by commenters that it would be impossible to determine the costs and resources that would be needed to comply with CMS's corrective action plan requirements without clarifying those requirements, we outlined the requirements. See 71 FR 51071. In addition, in § 431.992 of the August 28, 2006 interim final rule, we made a good faith estimate of the burden on States to comply with our corrective action plan requirements. See 71 FR 51078.

Comment: A commenter stated that, although administrative cost has been diminished, States will be challenged to evaluate the results and formulate corrective action plans. According to the commenter, this will significantly affect small SCHIP programs with few full-time equivalent positions.

Response: We believe that, even without the requirements placed on them by the PERM program, States would need to take corrective actions to reduce improper payments as a matter of prudently administering the SCHIP program. The findings under the PERM program can serve as a useful tool for all States to reduce improper payments and particularly for States that have no corrective action process currently in place. Further, a good corrective action process entails participation by a panel comprised of a variety of State positions so that no one person would be committed to the process on a full-time basis.

4. Recoveries

Comment: Several commenters noted that States are allowed only to dispute error findings with a difference of more than $100. However, according to the commenters, approximately 10 percent of the PAM and PERM pilot errors were identified as more than $100. The commenters believe that recovery is not cost effective since the Federal share must be refunded within 60 days from the date the overpayment was identified. The commenters recommend that CMS consider a minimal dollar amount, and that the overpayments under $100 should be exempt from recovery and payback of the Federal share.

Response: The $100 threshold applies only to appeals to CMS as part of the difference resolution process. In terms of recoveries, the current requirements are longstanding and the recovery of improper payments identified through the PERM FFS and managed care reviews fall under these requirements. The PERM program is not intended to make revisions to the recoveries requirements. Therefore, we are not adopting this recommendation.

Comment: A commenter recommended that the billing provider be used as the sampling unit so that the billing provider would be able to return the potential overpayment since they initially received it, rather than the provider who performed the service.

Response: Since we are measuring improper payments, the claim is the sampling unit. States are responsible for ensuring recoveries are made to CMS and can recoup or offset the improper payment from the provider.

Comment: A commenter stated that the relationship between States and the Federal government is deteriorating due to the recent Federal auditing and oversight activities (for example, PERM, Medicare and Medicaid program integrity, oversight by CMS, and the General Accounting Office and MEQC audits).

Response: PERM was developed to implement the IPIA. Recent laws such as the IPIA are intended to improve fiscal oversight, to identify fraud and abuse, and to protect taxpayer dollars. States can also benefit since the programs are also funded with State dollars. CMS is committed to maintaining a positive and strong partnership with the States.

IV. Provisions of This Final Regulation

We published a second interim final rule with comment on August 28, 2006 to respond to comments on the October 5, 2005 first interim final rule with comment, to announce that we would measure SCHIP in the same State that would be measured for Medicaid in any given year under PERM, and to set forth the methodology under which eligibility would be reviewed. We invited further comments on the eligibility methodology.

This final rule responds to the public comments on the August 28, 2006 interim final rule (71 FR 51050) and finalizes requirements that States must meet for submitting claims and policies to the CMS Federal contractors for purposes of conducting fee-for-service (FFS) and managed care reviews. This final rule also finalizes the State requirements for conducting eligibility reviews and estimating case and payment error rates due to errors in eligibility determinations.

In the preamble, we summarize the regulatory history of the States' requirements under the PERM program and describe the basis for the national contracting strategy, the selection and rotation of States once every 3 years for Medicaid and SCHIP, the PERM measurement cycle, the methodology for measuring eligibility under the PERM program and information States must submit to support the improper payments measurement under PERM.

This final rule:

- Revises subpart P, § 431.812(b) to add a provision that the negative case action eligibility reviews under PERM can be considered as meeting the negative case action review requirements of this section for purposes of the MEQC program;
- Deletes the requirement under § 431.970(a)(1) that States submit FFS claims stratified by service; and
- Revises the definition of negative case universe under § 431.978(d)(2).

V. Collection of Information Requirements

This document does not impose any new information collection and recordkeeping requirements. The information collection requirements associated with the interim final rule that published on August 28, 2006 (71 FR 51077), have received OMB approval and consequently, need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Note: The OMB approved numbers for the collections of information outlined in the August 28, 2006, interim final rule are as follows: (1) The burden associated FFS and corrective action plan is approved under OMB #0938–0974 with an expiration date of 10/31/2008; (2) The burden associated with managed care and corrective action plan is approved under OMB #0938–0994 with an expiration date of 9/30/2009; and (3) The burden associated with eligibility and corrective action plan is approved under OMB #0938–1012 with an expiration date of 1/31/2010.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). For the reasons discussed below, we have determined that this final rule is not a major rule.

1. Cost Estimate for FFS Reviews

We have estimated that it will cost $17.4 million annually ($16,396,933 in Federal cost and $976,528 in State cost) to review FFS claims and estimate error rates in 34 States (17 States for Medicaid and 17 States for SCHIP). This estimate is based on the Federal cost of engaging the Federal contractors to conduct the reviews and calculate the error rates, and the State cost to submit requested information to support the reviews. We estimated these costs as follows:

Through the use of Federal contractors, we estimated that for the FFS measurement it would cost $15,075,748 in Federal funds ($7,537,874 per program). This estimate is based on our experience to date with the Federal contractors that have been engaged to work on the PERM project. Based on an average of 1,000 claims reviewed per State plus travel and other administrative expenses, the FFS error rate estimates for 34 States would cost approximately $15,075,748 in Federal funds for the Federal contracting cost.

Under the national contracting strategy, we anticipate State cost to be the cost associated with submitting information. We estimated the cost to respond to requests for information for the Medicaid and SCHIP FFS reviews is $2,297,713 ($1,321,185 in Federal cost and $976,528 in State cost). Therefore, the estimated total Federal cost is $16,396,933 and total State cost is $976,528 for FFS measurement.

2. Cost Estimate for Managed Care Reviews

We have estimated that it will cost $5.7 million annually ($5,275,571 in Federal cost and $389,414 in State cost) to estimate managed care error rates for 34 States (17 States for Medicaid and 17 States for SCHIP). This is based on the Federal cost of engaging the Federal contractors to conduct the reviews and calculate the error rates, and the State cost to submit requested information to support the reviews. We estimated these costs as follows:

We estimated that it will cost $4,748,718 in Federal funds annually for a Federal contractor to estimate the error rates for 34 States. We assumed that we will use the same statistical contractor and the same review contractor for managed care and FFS reviews in each program to gain cost efficiencies in administration, overhead and systems. Based on an average of 500 claims reviewed per State plus travel and other administrative expenses, we estimate that it would cost $4,748,718 in Federal funds for the Federal contracting cost.

Under the national contracting strategy, we anticipate State cost to be the cost associated with submitting information, similar to the cost for FFS reviews. As we indicated in the information collection section of this rule, we estimated the cost to respond to requests for information for the managed care reviews would be $916,267 ($526,853 in Federal cost and $389,414 in State cost). Therefore, the estimated total Federal cost is $5,275,571 and total State cost is $389,414 for managed care measurement.

3. Cost Estimate for Eligibility Reviews

Beginning in FY 2007, States will review eligibility in the same year they are selected for FFS and managed care reviews in Medicaid and SCHIP. We estimated that total cost for eligibility review for 34 States is $18.6 million ($10,682,957 in Federal cost and $7,896,098 in State cost). This cost estimate is based on the cost for States to submit information to CMS and the cost for States to conduct eligibility reviews and report rates to CMS. These costs are estimated as follows:

We estimated in the information collection section, that the annualized number of hours required to respond to requests for information for the eligibility review (for example, sampling plan, monthly sample lists, the eligibility corrective action report) for 34 States will be 108,800 hours (3,200 hours per State per program). At the 2007 general schedule GS–12–01 rate of pay that includes fringe and overhead costs ($41.46/hour), we calculated a cost of $4,510,848 ($2,593,738 in Federal cost and $1,917,110 in State cost). This cost estimate includes the following estimated annualized hours: (1) Up to 1,000 hours required for States to develop and submit a sampling plan; (2) up to 1,200 hours for States to submit 12 monthly sample lists detailing the cases selected for review; and (3) up to 1,000 hours for States to submit a corrective action plan for purposes of reducing the eligibility payment error rate.

For the eligibility review and reporting of the findings, we estimated that each State would need to review an annual sample size of 504 active cases to achieve a 3 percent margin of error at a 95 percent confidence interval level in the State-specific error rates. We also estimated that States would need to review 204 negative cases to produce a case error rate that met similar standards for statistical significance. We estimated that for 34 States the annualized number of hours required to complete the eligibility case reviews and report the eligibility-based error rates to CMS would be 339,320 hours (9,980 hours per State, per program). At the 2007 general schedule GS–12–01 rate of pay that includes fringe and overhead costs ($41.46/hour), we calculated a cost of $14,068,207 ($8,089,219 in Federal cost and $5,978,988 in State cost).

Therefore, the total annual estimate of the cost for 34 States to submit information and to conduct the eligibility reviews and report the error rate to CMS is $18,579,055 ($10,682,957 in Federal cost and $7,896,098 in State cost).

4. Cost Estimate for Total PERM Costs

Based on our estimates of the costs for the FFS, managed care and eligibility reviews for both the Medicaid and SCHIP programs at approximately $41.6 million ($32,355,461 in Federal cost and $9,262,040 in State cost), this rule does not exceed the $100 million or more in any 1 year criterion for a major rule, and a regulatory impact analysis is not required.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6.5 million to $31.5 million in any 1 year. Individuals and States are not included in the definition of a small entity.

We stated in the August 27, 2004 proposed rule that providers could be required to supply medical records or other similar documentation that verified the provision of Medicaid or SCHIP services to beneficiaries as part of the PERM reviews, but we anticipated this action would not have a significant cost impact on providers. Providers would only need to provide medical records for the FFS component of this program. A request for medical documentation to substantiate a claim for payment would not be a burden to providers nor would it be outside the customary and usual business practices of Medicaid or SCHIP providers. Not all States would be reviewed every year and medical records would only be requested for FFS claims, so it would be unlikely for a provider to be selected more than once per program to provide supporting documentation, particularly in States with a large Medicaid or SCHIP managed care population.

In addition, the information should be readily available and the response should take minimal time and cost since the response would merely require gathering the documents and either copying and mailing them or sending them by facsimile. Therefore, we have concluded in this final rule that the provision of medical documentation by providers is within the customary and usual business practice of a provider who accepts payment from an insurance provider, whether it is a private organization, Medicare, Medicaid, or SCHIP and should not have a significant impact on the provider's operations. Therefore, we have determined, and the Secretary certifies, that an impact analysis is not required under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

These entities may incur costs due to collecting and submitting medical records to the contractor to support medical reviews; but, like any other Medicaid or SCHIP provider, we estimate these costs would not be outside the limit of usual and customary business practices. Also, since the sample is randomly selected and only FFS claims are subject to medical review, we do not anticipate that a great number of small rural hospitals would be asked for an unreasonable number of medical records. As stated before, a State will be reviewed only once, per program, every 3 years and it is highly unlikely for a provider to be selected more than once per program to provide supporting documentation. Therefore, we have determined, and the Secretary certifies, that an impact analysis is not required under section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $120 million or more. This final rule does not impose costs on States to produce the error rates for FFS and managed care payments, but only requires States and providers to submit information already on hand to the contractor so that the error rates can be calculated. The costs associated with submitting information for copying and mailing the information or for sending the information by facsimile are minimal.

Based on our estimates of State participation burden for both Medicaid and SCHIP, for 34 States (17 States per Medicaid and 17 States for SCHIP), for the FFS reviews ($976,528), the managed care reviews ($389,414), and eligibility ($7,896,098), we calculated that the annual burden for these States for the PERM program is approximately $9,262,040 in State costs for both Medicaid and SCHIP. The combined costs of both programs total approximately $544,826 for each of the

17 States. Thus, we do not anticipate State costs to exceed $120 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements on State and local governments, preempts State law, or otherwise has Federalism implications. The proposed rule, which would have imposed significantly more cost burden on States to measure improper payments, had estimated costs of $1 million to $2 million per State. This final rule significantly reduces these costs by requiring States only to submit information to support the medical and data processing reviews. The costs and burden associated with submitting this information are the time and costs to copy and mail the information or, at State option, submit the information electronically.

This final rule does require States selected for review to submit an eligibility sampling plan, monthly sample selection information, summary review findings, State error rate calculations, and other information in order for CMS to calculate the eligibility national error rate. We estimated that the burden to conduct the eligibility measurement for Medicaid and SCHIP for 34 States will be approximately $18,579,055 ($10,682,957 in Federal cost and $7,896,098 in State cost). As a result, we assert that this regulation will not have a substantial impact on State or local governments.

B. Anticipated Effects

The final rule is intended to measure improper payments in Medicaid and SCHIP. States would implement corrective actions to reduce the error rate, thereby producing savings over time. These savings cannot be estimated until after the corrective actions have been monitored and determined to be effective, which can take several years.

C. Conclusion

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 457

Administrative practice and procedure, Grant programs—health, Health insurance, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services confirms as final the interim final rules published on October 5, 2005 (70 FR 58260) and August 28, 2006 (71 FR 51050), with the following amendments to 42 CFR chapter IV:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 1. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart P—Quality Control

■ 2. Section 431.812 is amended by revising paragraph (b) to read as follows::

§ 431.812 Review procedures.

* * * * *

(b) *Negative case reviews.* Except as provided in paragraph (c) of this section, or unless a State is utilizing an approved sampling plan to conduct negative case action reviews under § 431.978(a) and § 431.980(b), the agency must review those negative cases selected from the State agency's list of cases that are denied, suspended, or terminated in the review month to determine if the reason for the denial, suspension, or termination was correct and if requirements for timely notice of negative action were met. A State's negative case sample size is determined on the basis of the number of negative case actions in the universe.

* * * * *

Subpart Q—Requirements for Estimating Improper Payments in Medicaid and SCHIP

■ 3. Section 431.970 is amended by revising paragraph (a)(1) to read as follows:

§ 431.970 Information submission requirements.

(a) * * *

(1) All adjudicated fee-for-service (FFS) and managed care claims information, on a quarterly basis, from the review year;

* * * * *

■ 4. Section 431.978 is amended by revising paragraph (d)(2) to read as follows:

§ 431.978 Eligibility sampling plan and procedures.

* * * * *

(d) * * *

(2) *Eligibility universe—negative cases.* The Medicaid and SCHIP negative universe consists of all negative cases for the sample month. The negative case universe is not stratified.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.767, State Children's Health Insurance Program)

Dated: April 10, 2007.

Leslie Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 15, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07–4240 Filed 8–24–07; 4:00 pm]

BILLING CODE 4120–01–P